08/24/05

Attorney's Docket No. SP-1093 US CIP 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	Wong, et al.
Serial No.	:	09/912,471
Art Unit	:	1651
Examiner	:	Deborah K. Ware
For	:	Method for Producing Ultrapure Protein Material

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Dated: 8/23/05

Sheri West

Docket No. SP-1093 US CIP 2 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Examiner:	Deborah K. Ware
Group Art Unit:	1651
Applicants:	Wong et al.
Serial No.:	09/912,471
Filed:	July 24, 2001
For:	METHOD FOR PRODUCING ULTRAPURE PROTEIN MATERIAL

"Express Mail" Label No. **EV 042959045 US**
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By _____
Typed Name: **Sheri West**

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Alexandria, VA 22313-1450

TRANSMITTAL OF AMENDED APPEAL BRIEF

1. Transmitted herewith is an Amended Appeal Brief with respect to a Notification of Non-Compliant Appeal Brief, mailed June 28, 2005. This Amended Appeal Brief takes the place of the Appeal Brief filed April 15, 2005, based on a Notice of Appeal filed on November 16, 2004.

2. **STATUS OF APPLICANT**
This application is on behalf of other than a small entity.

3. **FEE FOR FILING APPEAL BRIEF**
The Appeal Brief filing fee was paid on April 15, 2005 in the submission of the Appeal Brief.

08/25/2005 HAHHED1 00000027 500421 09912471
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4. EXTENSION OF TERM

Applicant petitions for a one month extension of time under 37 CFR 1.136

Fee: $120.00

If an additional extension of time is required, please consider this a petition therefor.

Extension fee due with this request $ 120.00

5. Total fee due

The total fee due is

Appeal brief fee $ None (previously paid)
Extension fee $ 120.00

TOTAL FEE DUE $ 120.00

6. FEE PAYMENT

Authorization is hereby made to charge the amount of $120.00 to Deposit Account No. 50-0421. Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.

7. FEE DEFICIENCY

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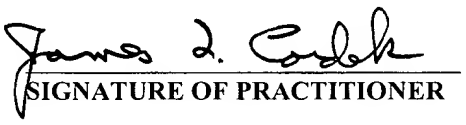

SIGNATURE OF PRACTITIONER

Date: August 23, 2005

James L. Cordek
(type or print name of practitioner)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Examiner:	Deborah K. Ware
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By _____
Typed Name: **Sheri West**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

AMENDED APPEAL BRIEF

This Amended Appeal Brief is in response to a Notification of Non-Compliant Appeal Brief, mailed June 28, 2005, for which a one month period of response is given.

On November 16, 2004, Appellant appealed from the final rejection of claims 81-93 and 96-124.

TABLE OF CONTENTS

REAL PARTY IN INTEREST

Solae, LLC, a corporation of the State of Delaware located at P. O. Box 88940 St. Louis, MO 63188, is the real party in interest in the appeal of the present application, having been assigned the application by the inventors.

RELATED APPEALS AND INTERFERENCES

There was a Decision on Appeal for patent application U.S. Serial No. 09/785,936 as Appeal No. 2004-0450, which is related to the present application. The present patent application, as U.S. Serial No. 090/912,471; U.S. Serial No. 09/912,494; and U.S. Serial No. 09/785,936 claim priority from patent application U.S. Serial No. 08/996,976 filed December 23, 1997 (now abandoned), where both the present application and U.S. Serial No. 09/912,494 are continuations-in part applications of U.S. Serial No. 08/996,976 and U.S. Serial No. 09/785,936 is a divisional application of U.S. Serial No. 08/996,976.

A copy of Appeal No. 2004-04540 is enclosed under the heading Related Proceeding Apppendix.

STATUS OF CLAIMS

Claims 1-80 were originally filed in the present application. On October 2, 2002, a Restriction was made between Group I (claims 1 and 3-36) and Group II (claims 37-80). On November 1, 2002, Applicant elected the claims of Group I and withdrew claims 37-80. On October 31, 2003, Applicant cancelled claims 1-80 and added claims 81-132. In an Office Action dated January 28, 2004, a Restriction was made between Group I (claims 81-124) and Group II (claims 125-132). On March 30, 2004, Applicant elected the claims of Group I and cancelled claims 125-132. Applicant further cancelled claims 94 and 95. A final Office Action was mailed on August 8, 2004. A response, but with no amendment was made on November 16, 2004. Claims 81-93 and 96-124 remain pending in the present application and are the subject of this appeal. A copy of the pending appealed claims is attached in Appendix A. No claims are allowed.

STATUS OF AMENDMENTS

A response after final rejection was filed on November 16, 2004. No amendment to the claims was submitted in that response.

SUMMARY OF CLAIMED SUBJECT MATTER

This invention relates to a method for reducing the concentrations of ribonucleic acids and minerals bound to ribonucleic acids from a vegetable protein material. A vegetable protein material is provided and is slurried in an aqueous solution. The slurry is treated with an enzyme preparation containing an acid phosphatase at a pH and a temperature and for a time effective to substantially reduce the ribonucleic acid concentrations in the vegetable protein material. The treated slurry is then washed to provide a vegetable protein material having a reduced concentration of ribonucleic acids.

In a preferred embodiment of the invention, the mineral content of the vegetable protein material is reduced by treatment of the vegetable protein material slurry with the enzyme preparation containing an acid phosphatase.

In another preferred embodiment of the invention, the vegetable protein material is a soy protein, the pH at which the slurry is treated with the enzyme preparation is from about 3 to about 6, the temperature at which the slurry is treated with the enzyme preparation is from about 20°C to about 70°C, and the time period over which the slurry is treated with the enzyme preparation is from about 30 minutes to about 4 hours. The treated slurry is washed after being treated with the enzyme preparation.

In yet another preferred embodiment, the slurry is heat treated after being enzymatically treated and washed, and the heat treated slurry is dried.

In another aspect, the invention is a method for reducing the concentrations of phytic acid, phytates, ribonucleic acids, and minerals bound to phytic acid, phytates, and ribonucleic acids from a vegetable protein material. A vegetable protein material is provided and is slurried in an aqueous solution. The slurry is treated with an enzyme preparation containing an acid phosphatase and a phytase at a pH and a temperature and for a time effective to substantially reduce the phytic acid, phytate, and ribonucleic acid concentrations in the vegetable protein material.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether under 35 U.S.C. §102(b) the subject matter of claims 81-93 and 96-124 are anticipated by EP 0 380 343.

2. Whether under 35 U.S.C. §103(a) the subject matter of claims 81-93 and 96-124 are obvious to one of ordinary skill in the art over EP 0 380 343.

ARGUMENT

EP 0 380 343 A2

EP 0 380 343 A2 (the '343 patent) teaches a method for production of phytate-free or low-phytate soy protein isolates or soy protein concentrates. The '343 patent is directed to a method of degrading phytates with one or more phytate-degrading enzymes, where acid phosphatases are disclosed as one type of phytate-degrading enzyme. The '343 patent does not disclose or mention ribonucleic acids at all.

First Ground of Rejection

Claims 81-93 and 96-124 are rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 380 343.

Claim 81 and its dependent claims 82-93 and 96-124 provide methods for producing a soy protein material in which an aqueous slurry of a soy protein material is treated with an enzyme preparation containing an acid phosphatase enzyme to degrade ribonucleic acids in the soy protein material, and then the soy protein material is washed to remove degraded ribonucleic acids.

Claim 81 and its dependent claims are not explicitly anticipated by the '343 patent since the '343 patent does not disclose ribonucleic acids at all, and clearly does not teach any means of degrading ribonucleic acids or washing a soy protein material to remove degraded ribonucleic acids. Therefore, the only possible basis for anticipation is that the claims are inherently anticipated by the '343 patent.

Claim 81 and its dependent claims, however, are not inherently anticipated by the '343 patent since the process disclosed by the '343 patent does not necessarily result in the degradation of ribonucleic acids in a soy protein material by an enzyme preparation containing an acid phosphatase. Anticipation by inherency applies when a claimed element is "always present" and "naturally flows" from the prior art disclosure. Inherency may not be established by probabilities or possibilites—the mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). More particularly, for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of

what was deliberately intended as disclosed in the prior art reference. *Mehl/Biophile International Corp. v. Milgraum*, 52 USPQ2d 1303, 1307 (CAFC 1999). Occasional results are not inherent. *Id.* at 1306. See also *Trintec Industries Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597, 1599 (CAFC 2002); *In Re Robertson*, 49 USPQ2d 1949, 1950-51 (CAFC 1999); *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1679-81 (CAFC 2002); and *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1748-1750 (CAFC 1991).

The Office Action clearly shows that the basis for the §102(b) rejection is that the EP 0 380 343 reference teaches a process that produces the presently claimed processes wherein ribonucleic acids in a soy protein material are reduced by degrading the ribonucleic acids with an enzyme preparation containing an acid phosphatase enzyme because the reference utilizes a FINASE® enzyme preparation that contains an acid phosphatase to degrade phytates in an aqueous slurry of soy protein material. Applicants note, however, that the reference teaches a process that may utilize an enzyme preparation that contains an acid phosphatase enzyme in a soy protein material, but does not teach that the enzyme preparation must contain an acid phosphatase enzyme—and, therefore, the claims of the present application are not inherently anticipated by the cited reference.

The reference does not limit the enzyme preparations used to reduce phytates in soy protein to FINASE® enzyme preparations. Specifically, on page 6, lines 38-41 the EP 0 380 343 A2 reference states:

> Stated most simply, in its broadest terms, the present invention comprises:
> (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes (emphasis added): and
> (b) isolating the resulting phytate-free or low phytate soy protein.

The reference explains what phytate-degrading enzymes are, with respect to the invention of the reference (page 6, lines 16-27):

> In the various aspects of the present invention, phytic acid is eliminated by means of effective commercially available bulk enzyme compositions. Phytate-degrading enzymes dephosphorylate inositol-hexaphosphate to yield inositol and orthophosphate, several forms of

> inositolphosphates being the intermediate products. Phytate degrading enzymes include phytase and acid phosphatases.
>
> Phytase and acid phosphatases are produced by various microorganisms such as Aspergillus spp., Rhizopus spp., and yeasts (Appl. Microbiol. 16: 1348-1357 (1968 Enzyme Microb. Technol. 5: 377-382 (1983)), and phytase is also produced by various plant seeds, for example wheat, during germination. According to methods known in the art, enzyme preparations can be obtained from the above mentioned organisms. Caransa et al. Netherlands Pat. Appl. 87.02735, found that at the same enzyme dosage phytase from Aspergillus spp. degraded phytic acid in corn more efficiently than phytase from wheat.
>
> Particularly preferred for the purposes of the present invention are the Finase enzymes, formerly termed Econase EP 43 enzymes (emphasis added), manufactured by Alko Ltd., Rajamaki, Finland.

Thus, the reference discloses that use of the FINASE® enzyme preparations is a preferred method of practicing the disclosed invention, but that the process of the reference is not limited to use of FINASE® enzymes and can utilize any phytate-degrading enzyme preparation containing one or more phytate-degrading enzymes, where such enzyme preparations can be produced from *Aspergillus spp.*, *Rhizopus spp.*, yeasts, and various plant seeds such as wheat.

These enzyme preparations do not necessarily contain an acid phosphatase enzyme effective to degrade ribonucleic acids in a vegetable protein material. The reference itself implies that enzyme preparations useful in the process of the reference that contain phytase, but not acid phosphatase, can be derived from various plant seeds, for example wheat, during germination. The absence of acid phosphatase enzymes in these plant seed phytase enzyme preparations can be inferred from the sentence in which it is disclosed that phytase and acid phosphtases are produced by various microorganisms, yet the plant seed enzyme preparations are disclosed as only containing phytases (EP 0 380 343 A2 p. 6, lines 20-22). As such, it is clear that the reference discloses enzyme preparations containing no acid phosphatase enzymes among the enzyme preparations that are effective to practice the method of reducing phytates and phytic acid in accordance with the method of the reference.

Even enzyme preparations derived from microorganisms such as *Aspergillus spp.* do not necessarily contain an acid phosphatase enzyme effective to practice the claimed invention. There are numerous strains of phytase producing *Aspergillus spp.*, including *Aspergillus oryzae, Aspergillus niger, Aspergillus flavus, Aspergillus terrus, Aspergillus*

carneus, and *Aspergillus fumigatus*, not all of which produce enzyme preparations containing acid phosphatase that are effective to degrade ribonucleic acids in accordance with the present invention. For example, NAUTUPHOS® is an enzyme preparation that is commercially sold as a phytase (*see* Exhibit A attached hereto) that is derived from *Aspergillus niger*, yet does not degrade ribonucleic acid in a vegetable protein material in accordance with the current claims (*see* Theodore M. Wong declaration, Exhibit B attached hereto). Such phytate-degrading enzyme preparations clearly fall within the description of the process of the reference since they degrade phytates and phytic acid when utilized in accordance with the disclosed process (*see* Exhibit B).

The cited reference, therefore, clearly does not intend to limit the disclosed method of reducing phytates and phytic acids to using only FINASE® enzyme preparations. Page 6, lines 16-27, of the EP 0 380 343 A2 reference certainly indicates that other phytase enzyme preparations were contemplated for use in the disclosed process, particularly since FINASE® is derived from *Aspergillus niger*, yet the reference discloses many other sources of phytase enzymes. Furthermore, claim 3 of the cited reference states that the method of the reference is intended to include enzymes originating from *Aspergillus spp., Rhizopus spp.,* and yeast. Therefore, the deliberate intent of the cited reference, to degrade phytates and phytic acid, can be achieved utilizing other enzyme preparations that do not degrade ribonucleic acids or do not contain an acid phosphtase enzyme (e.g. NATUPHOS® enzyme).

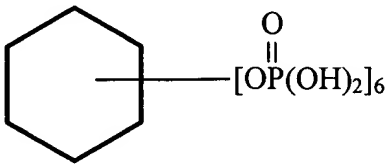
The Examiner may have reached this conclusion as well, since page 6 lines 7-9 of the Office Action of February 7, 2003 states "Further, in view of the teaching of FINASE in the cited EP reference it is apparent that the preparation may indeed include an acid phosphatase". Under the case law cited above, the fact that the process of the cited EP reference may indeed contain an acid phosphatase is insufficient to establish inherent anticipation. The process of the cited reference must always contain an acid phosphatase in order to establish inherent anticipation.

Furthermore, even if the FINASE enzyme preparation disclosed in the '343 patent as a preferred enzyme preparation always degrades ribonucleic acids in the slurry of soy

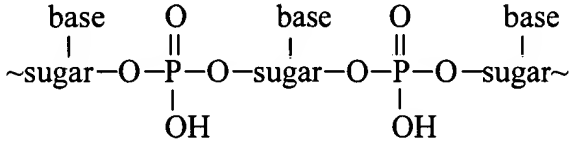
protein material, the '343 patent disclosure of the use of the FINASE enzyme preparation in a soy material is insufficient to establish inherent anticipation because the deliberate intent of the '343 patent is to degrade phytates with one or more phytate-degrading enzymes, which can be accomplished, as discussed above, with other non-FINASE enzymes that do not result in the degradation of ribonucleic acids. It is irrelevant to a determination of anticipation by inherency if a FINASE enzyme preparation always degrades ribonucleic acids in an aqueous slurry of a soy protein material in the process taught in the '343 patent because the deliberate intent of the '343 reference is to degrade phytates in a soy protein material with one or more phytate degrading enzymes that are not limited to FINASE enzyme preparations. As the Mehl/Biophile case requires, inherent anticipation is determined in accordance with the deliberate intent of the cited reference, and clearly the cited reference deliberately intended to include enzyme preparations beyond FINASE enzyme preparations as useful for degrading phytates in a soy protein material. Therefore, degradation of ribonucleic acids is not a necessary consequence of the deliberate intent of the process of the '343 patent, and the disclosure of the '343 patent does not inherently anticipate the present invention.

It is the opinion of the Patent Office that while EP '343 does not disclose ribonucleic acids, or to a use of an enzyme to degrade them that nevertheless RNAs would be degraded simply because RNAs contain phosphorus groups and the EP '343 use phosphatase enzyme. In EP '343 phosphatase enzymes are used to reduce or eliminate phytates in soy proteins. Phytates are phytic acid or the calcium, magnesium and potassium salts of phytic acid, the latter of which are called phytin.

Phytic acid is represented by the below structure and has a molecular weight of 660.



Ribonucleic acid is a polynucleotide chain of ribose, phosphoric acid and organic bases of purines (adenine and guanine) and pyrimidines (cytosine and uracil). A representation of RNA is below.



RNA like DNA is a long unbranched macromolecule consisting of nucleotides joined by 3'- 5' phosphodiester bonds. The number of nucleotides in RNA varies from 75 to thousands. RNA has a hydroxyl group at C-2 of ribose that is not present in DNA. DNA is capable of forming a double stranded molecule. Because of the extra hydroxyl group in RNA, RNA is too bulky to form a double stranded molecule. While RNA is single stranded, parts of it can bend and form loops where the bases can pair up with each other. Further, the positions of the bases are stabilized by hydrogen bonding.

RNA is thus a very large and bulky molecule whereas phytic acid is not. Phytase enzyme is able to easily react with phytic acid to degrade phytic acid. Because of hydrogen bonding and steric hindrance, one would not expect phytase to degrade RNA. One would not look to non-analogous art (EP '343) to solve the problem of degrading RNA as per the instant invention.

RNAs and phytic acid both contain phosphorous groups. However, one skilled in the art would not utilize the teachings of EP '343 of enzymes and phytic acid to arrive at the present invention of enzymes RNAs. Phosphorous groups aside, phytic acid and RNAs are very different chemical entities. Chemistry is largely empirical and therefore there is often great difficulty in predicting how a given compound will behave. *In re Carleton* (CCPA 1979) 599 F2d 1021, 202 USPQ 165. Further, because chemistry is often an empirical science, it is easy to characterize inventions in the field of chemistry as the result of "routine testing". But even "routine testing "must be guided and directed by the mental concept of the inventor. "Routine experimentation" does not negate

patentability. 35 USC 103, last sentence; *In re Fay et al.* (CCPA 1965) 347 F2d 597, 146 USPQ 47. Reconsideration and withdrawal of rejection is respectfully requested.

Second Ground of Rejection

Claims 81-93 and 96-124 are rejected as being unpatentable under 35 U.S.C. §103(a) over EP 0 380 343.

Claim 81 and its dependent claims 82-93 and 96-124 are rejected as obvious over the '343 patent since allegedly any difference between the claims and the '343 patent is considered to be so slight as to render the claims *prima facie* obvious over the '343 patent. As noted above, however, the '343 patent provides no disclosure at all relating to degrading ribonucleic acids. One skilled in the art would learn absolutely nothing about how to degrade ribonucleic acids from the '343 patent, and thus one skilled in the art would never look to the '343 patent for any guidance in determining an effective method for degrading ribonucleic acids in a soy protein material. Therefore, no basis whatsoever has been established for a case of *prima facie* obviousness based on the disclosure of the '343 patent.

Appellant states that the instant claims are not obvious under 35 USC §103(a) over EP 0 380 343. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

SUMMARY

In view of the discussion of the reference, coupled with Appellant's response, Appellant states that the Examiner's rejection of claims 81-93 and 96-124 are not anticipated under 35 U.S.C. §102(b), over EP 0 380 343, or, in the alternative, are not obvious under 35 U.S.C. §103(a) over EP 0 380 343 and reversal of the Examiner's decision is respectfully requested.

If any additional fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-0421.

Respectfully submitted,
Solae, LLC

Date: August 23, 2005

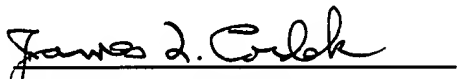


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Exhibit A

Claims Appendix

CLAIMS APPENDIX

Claims 1-80 (cancelled)

Claim 81 (previously added) A method for producing a soy protein material comprising,

forming an aqueous slurry of a soy protein material

treating the slurry with an enzyme preparation containing an acid phosphatase enzyme at a temperature, a pH, and for a time period effective for said enzyme preparation to degrade ribonucleic acids in the soy protein material; and

washing the soy protein material to remove degraded ribonucleic acids.

Claim 82 (previously added) The method of claim 81 wherein said protein material is a soy protein concentrate or a soy protein isolate.

Claim 83 (previously added) The method of claim 81 wherein said slurry contains from about 2% to about 30% of the protein material by weight.

Claim 84 (previously added) The method of claim 83 wherein said slurry contains from about 5% to about 20% of the protein material by weight.

Claim 85 (previously added) The method of claim 83 wherein said slurry contains from about 10% to about 18% of the protein material by weight.

Claim 86 (previously added) The method of claim 81 wherein treatment of said slurry with said enzyme preparation is effective to degrade a majority of ribonucleic acids in said soy protein material.

Claim 87 (previously added) The method of claim 86 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy protein material from which a majority of ribonucleic acids have been removed.

Claim 88 (previously added) The method of claim 81 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 60% of ribonucleic acids in said soy protein material.

Claim 89 (previously added) The method of claim 88 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy protein material from which at least 60% of ribonucleic acids have been removed.

Claim 90 (previously added) The method of claim 81 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 70% of ribonucleic acids in said soy protein material.

Claim 91 (previously added) The method of claim 90 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy protein material from which at least 70% of ribonucleic acids have been removed.

Claim 92 (previously added) The method of claim 81 wherein treatment of said slurry with said enzyme preparation is effective to degrade at least 80% of ribonucleic acids in said soy protein material.

Claim 93 (previously added) The method of claim 92 wherein washing the treated slurry is effective to remove said degraded ribonucleic acids to provide a soy protein material from which at least 80% of ribonucleic acids have been removed.

Claims 94-95 (cancelled)

Claim 96 (previously added) The method of claim 81 wherein treatment of said slurry with said enzyme preparation is effective to degrade phytic acid and phytates in said soy protein material.

Claim 97 (previously added) The method of claim 96 wherein washing said treated slurry is effective to remove said degraded phytic acid and phytates to provide a soy protein material from which phytic acid and phytates have been removed.

Claim 98 (previously added) The method of claim 81 wherein said slurry is treated with an acid phosphatase at a pH of from about 3 to about 6.

Claim 99 (previously added) The method of claim 98 wherein said slurry is treated with an acid phosphatase at a pH of from about 3.5 to about 5.5.

Claim 100 (previously added) The method of claim 98 wherein said slurry is treated with an acid phosphatase at a pH of from about 4 to about 5.

Claim 101 (previously added) The method of claim 98 wherein said slurry is treated with an acid phosphatase at a pH of from about 4.4 to about 4.6.

Claim 102 (previously added) The method of claim 81 wherein said slurry is treated with an acid phosphatase at a temperature of from about 20°C to about 70°C.

Claim 103 (previously added) The method of claim 102 wherein said slurry is treated with an acid phosphatase at a temperature of from about 40°C to about 55°C.

Claim 104 (previously added) The method of claim 81 wherein said slurry is treated with an acid phosphatase wherein said acid phosphatase has an activity of about 600 KPU/g of curd solids to about 1400 KPU/g of curd solids.

Claim 105 (previously added) The method of claim 81 wherein said slurry is treated with an acid phosphatase wherein said acid phosphatase is present in said slurry in an amount of from about 0.1% to about 10% of the protein material, by weight.

Claim 106 (previously added) The method of claim 105 wherein said slurry is treated with an acid phosphatase wherein said acid phosphatase is present in said slurry in an amount of from about 0.3% to about 5% of the protein material, by weight.

Claim 107 (previously added) The method of claim 81 wherein said slurry is treated with said acid phosphatase for a period of from about 30 minutes to about 4 hours.

Claim 108 (previously added) The method of claim 107 wherein said slurry is treated with said acid phosphatase for a period of from about 45 minutes to about 3 hours.

Claim 109 (previously added) The method of claim 81 further comprising a step of drying said treated and washed slurry to provide a purified soy protein material.

Claim 110 (previously added) The method of claim 81 further comprising a step of heat treating said treated slurry.

Claim 111 (previously added) The method of claim 81 further comprising a step of treating said washed and acid phosphatase treated soy protein material slurry with a protease enzyme at a temperature, a pH, and for a time period sufficient to hydrolyze said protein in said slurry.

Claim 112 (previously added) The method of claim 111 wherein said protease enzyme is present in said slurry in a concentration of from about 0.1% to about 10% of the protein material in said slurry by dry weight.

Claim 113 (previously added) The method of claim 111 further comprising the step of heat treating the hydrolyzed protein slurry.

Claim 114 (previously added) The method of claim 111 further comprising the step of drying the hydrolyzed protein material after hydrolysis with said protease enzyme.

Claim 115 (previously added) The method of claim 81 wherein said treatment of said soy protein soy protein material slurry with an enzyme preparation containing an acid phosphatase and said wash of said treated slurry are effective to lower the mineral content in the soy protein material.

Claim 116 (previously added) The method of claim 81 wherein said soy protein material is washed by diluting said treated slurry with water and subsequently removing at least a portion of said diluent from said soy protein material.

Claim 117 (previously added) A method of producing a soy protein material comprising, treating an aqueous slurry of a soy protein material with an enzyme preparation containing an acid phosphatase enzyme at a temperature, a pH, and for a time period effective for said enzyme preparation to degrade ribonucleic acids in the soy protein material.

Claim 118 (previously added) The method of claim 117 wherein said soy protein material is a soy protein concentrate or a soy protein isolate.

Claim 119 (previously added) The method of claim 117 wherein treatment of the slurry with said enzyme preparation is effective to degrade a majority of ribonucleic acids in the soy protein material.

Claim 120 (previously added) The method of claim 117 wherein treatment of the slurry with said enzyme preparation is effective to degrade at least 80% of ribonucleic acids in the soy protein material.

Claim 121 (previously added) The method of claim 117 wherein said enzyme preparation is effective to degrade phytic acid and phytates in said soy protein material.

Claim 122 (previously added) The method of claim 117 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase at a pH of from about 3 to 6.

Claim 123 (previously added) The method of claim 117 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase at a temperature of from about 20°C to about 70°C.

Claim 124 (previously added) The method of claim 117 wherein said slurry is treated with an enzyme preparation containing an acid phosphatase wherein said enzyme preparation has an activity of greater than 500 KPU/kg of protein material in said slurry.

Claims 125-132 (cancelled)

Exhibit B

Natuphos® Curricular

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

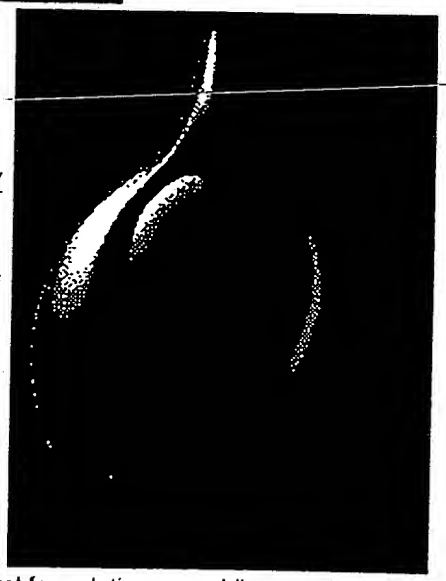
BASF Aktiengesellschaft

BASF

The natural key to higher yields

natuphos®

The original phytase



Our current product portfolio comprises:

- Natuphos®
- Natugrain®
- Natuphos Combi®
- Natustarch®
- Screensaver
- BASF Aktiengesellschaft
- DSM

Natuphos® offers the following benefits:

- Improvement of phosphorus digestibility in pig and poultry diets
- Quantified improvement of nutrient digestibility and energetic value of feed
- Saving of feed costs due to reduction of expensive feed ingredients in the feed formula
- Reduced excretion of phosphorus (over 30 % less)
- Outstanding bioefficacy

Natuphos® is available in a wide range of product formulations, providing powder, granule or liquid products of different phytase concentrations:
Natuphos® 5000
Natuphos® 5000 G
Natuphos® 5000 L
Natuphos® 10000 G*
Natuphos® 10000 L*

The original phytase
The development of Natuphos® was prompted by environmental problems in regions with high livestock density. Its microbial 3-phytase, obtained from *Aspergillus niger*, releases phosphorus from phytate, the storage form of phosphorus in vegetable feed compounds, which is more or less undigestible to pigs and poultry.
Thus, supplementation of feed with Natuphos® markedly increases the availability of phosphorus but also of other phytate-bound minerals and nutrients. Released from phytate, these nutrients can be efficiently used by the animal instead of being lost with the manure.

Reliable efficiency
The use of Natuphos® ensures a maximum release of digestible phosphorus from vegetable feedstuffs per phytase unit. Numerous feeding trials have shown the superior bioefficacy of Natuphos® compared to competitor products based on *Peniophora lycii* phytase. The mean exchange rate of Natuphos® versus Peniophora phytase in liquid products amounts to 1:1.5, in granular products it is at least 1:2.

[redacted]

Less phosphorus in the manure
Since Natuphos® improves phosphorus digestibility, feed supplementation with inorganic phosphorus can be reduced. In this way, Natuphos® decreases the excretion of phosphorus by over 30 %, providing ecological and economical benefits.

Feed optimisation with Natuphos®
Based on the results of numerous feeding trials, nutrient equivalencies have been

developed for Natuphos®. These figures express the extent to which nutrients are released by Natuphos® from phytate in the feed. They can be used in the same way as analysed nutrient contents of feed compounds to optimise least cost formulas. Feed optimisations reveal the economic advantages which can be gained by supplementing rations with Natuphos®.

Natuphos® formulations
Different formulations and concentrations of Natuphos® help to meet the customers' individual requirements for the manufacturing of quality feed under different production conditions:

POWDER
Natuphos® 5000:
fine, yellowish brown powder, recommended for use in non-pelleted compound feed and feed pelleted below 75°C
min. 5.000 FTU/g phytase activity

GRANULES
Natuphos® 5000 G:
fine white granules, recommended for use in compound feed pelleted up to 85°C
min. 5.000 FTU/g phytase activity
Natuphos® 10000 G*:
highly concentrated, fine white granules, recommended for use in concentrated premixes and in compound feed pelleted up to 85°C
min. 10.000 FTU/g phytase activity

LIQUIDS
Natuphos® 5000 L:
yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 5.000 FTU/g phytase activity
Natuphos® 10000 L*:
highly concentrated, yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 10.000 FTU/g phytase activity

*Available only outside the European Union

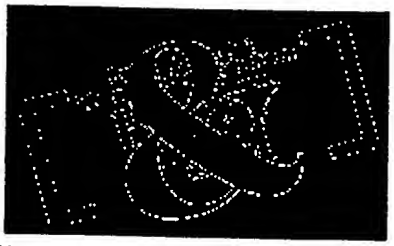


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Exhibit C

Theodore M. Wong Declaration

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	: Deborah K. Ware
Group Art Unit:	: 1651
Applicants	: Wong et al.
Serial No.	: 09/912,471
Filed	: July 24, 2001
For	: METHOD FOR PRODUCING ULTRAPURE PROTEIN MATERIALS

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 CFR §1.132

Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application.

2. I received a Bachelor of Arts Degree in Biology from Greensboro College in May, 1974, a Masters Degree in Microbiology from the University of Texas at Arlington in May 1976 and a Ph.D. Degree in Food Science/Food Biochemistry from Louisiana State University in May, 1982.

3. I have been employed by Solae, LLC, previously known as Protein Technologies International, Inc., since August 19, 1985, and currently hold the position of Senior Research Director, Product Development R&D.

4. Under my direction and control an experiment was conducted to determine the extent of degradation of phospho- and diphospho-ester nucleoside containing compounds in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solids ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase

enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then treated with bacterial alkaline phosphatase to degrade monomeric nucleotides to monomeric nucleosides and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the amount of monomeric nucleotides and monomeric nucleosides present in the sample ("Monomerics"). Another sample of each of the three samples was treated with a nuclease to hydrolyze polymeric ribonucleic acids to monomeric nucleotides, then was treated with pyrophosphatase to hydrolyze ribonucleoside containing adducts to monomeric nucleotides, then was treated with bacterial alkaline phospatase to hydrolyze the monomeric nucleotides to free monomeric nucleosides, and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the total amount of ribonucleoside containing compounds, both polymeric and monomeric, since the nuclease and pyrophosphatase treatments degrade the polymeric ribonucleoside-containing compounds to monomeric nucleotides, which are subsequently degraded to monomeric nucleosides with bacterial alkaline phosphatase ("Total"). The resulting ribonucleoside content by weight of nucleosides for each sample is shown in Table 1.

TABLE 1

Sample	Uridine	Cytidine	Guanosine	Adenosine	Total
Control					
--Monomerics	172	121	237	127	657
--Total	4302	5320	6711	5886	22219
Acid Phosphatase					
--Monomerics	5188	6886	7175	2204	21453
--Total	5281	7015	7599	2495	22390
Natuphos					
--Monomerics	231	128	240	184	783
--Total	4542	5628	6866	6070	23106

Table 1 shows that treatment with the acid phosphatase enzyme preparation produced a soy material product in which 95.8% [(21453/22390)*100] of all ribonucleoside containing compounds were either in their monomeric nucleoside form or their monomeric nucleotide form—clearly indicating the degradation of most polymeric ribonucleic acids in the soy material. Table 1 also shows that treatment with the NATUPHOS® phytase enzyme produced a soy material product in which 3.3% [(783/23106)*100] of all ribonucleoside containing products were either in their monomeric nucleoside form or their monomeric nucleotide form. The NATUPHOS® phytase enzyme degraded little or no polymeric ribonucleic acids, as can be shown by comparing amount of monomeric nucleosides and monomeric nucleotides in the soy material treated with NATUPHOS® to the Control, which contained 3.0% [(657/22219)*100] of all ribonucleoside containing products as monomeric nucleosides or monomeric nucleotides. NATUPHOS®, therefore, clearly did not degrade substantial amounts of ribonucleic acids to monomeric nucleosides or monomeric nucleotides, while the acid phosphatase enzyme preparation degraded almost all polymeric ribonucleoside-containing compounds to monomeric nucleosides and monomeric nucleotides.

5. Under my direction and control an experiment was conducted to determine the extent of degradation of phytic acid in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solid ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then analyzed to

determine phytic acid content, by weight percent of the soy protein material. The results are shown in Table 2.

TABLE 2

Sample	Phytic Acid (wt. %)
Control	1.46
Acid Phosphatase	0.12
Natuphos	0.11

Table 2 shows that both NATUPHOS® and the acid phosphatase enzyme preparation were effective to degrade phytic acid in a soy protein material relative to a soy protein material not treated with either enzyme. Tables 1 and 2, together, show that NATUPHOS® is effective to degrade phytic acid but not polymeric ribonucleoside-containing compounds such as ribonucleic acid, while an acid phosphatase enzyme preparation is effective to degrade both phytic acid and polymeric ribonucleoside-containing compounds such as ribonucleic acid.

Theodore M. Wong

Date: July 1, 2003

Exhibit D

Mehl/Biophile Int. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999)

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

LEXSEE 52 USPQ 2D 1303

MEHL/BIOPHILE INTERNATIONAL CORP., SELVAC ACQUISITIONS CORP. and NARDO ZAIAS, M.D., Plaintiffs-Appellants, v. SANDY MILGRAUM, M.D., PALOMAR MEDICAL TECHNOLOGIES, INC., and SPECTRUM MEDICAL TECHNOLOGIES, INC., Defendants-Appellees.

99-1038

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

192 F.3d 1362; 1999 U.S. App. LEXIS 24277; 52 U.S.P.Q.2D (BNA) 1303

September 30, 1999, Decided

SUBSEQUENT HISTORY: Rehearing Denied October 27, 1999, Reported at: *1999 U.S. App. LEXIS 31386.*

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of New Jersey. Judge Alfred M. Wolin.

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff medical device companies appealed an order from the United States District Court for the District of New Jersey dismissing their patent infringement action against defendant competitor on the ground that all of plaintiffs' patent claims were anticipated by prior art references.

OVERVIEW: Plaintiff medical device companies sued defendant competitor for infringement of a process patent for removing hair using a laser. Plaintiffs' claims were dismissed by summary judgment on the ground that all of the claims in plaintiffs' patent were anticipated by two prior art references, an instruction manual and an article, the manual being the dispositive anticipating reference. On appeal, the court upheld the dismissal, but concluded that the manual reference did not anticipate because it did not teach all the limitations of the claimed invention. However, there was no question of probabilities as to whether a person of ordinary skill following the teachings of the article would align the laser light applicator over a hair follicle as taught in the article reference. Thus, the article prior reference disclosed all of the elements of plaintiffs' claimed invention and its claims, including the dependent claims that were not argued separately, were invalid.

OUTCOME: Summary judgment for defendant affirmed; the article prior art reference anticipated claim one of the allegedly infringed patent in that a person of ordinary skill following the teaching of the article would align the laser light as taught in the reference and claimed in the invention; dependent claims were accordingly invalid.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment
Civil Procedure > Appeals > Standards of Review
[HN1] The appellate court reviews a district court's grant of summary judgment by reapplying the standard applicable at the district court.

Civil Procedure > Summary Judgment > Summary Judgment Standard
[HN2] Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. *Fed. R. Civ. P. 56(c).* In its review, the appellate court draws all reasonable inferences in favor of the non-movant.

Patent Law > Anticipation & Novelty > General Overview
[HN3] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either

explicitly or inherently. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it.

Patent Law > Anticipation & Novelty > General Overview

[HN4] Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.

Patent Law > Anticipation & Novelty > General Overview

[HN5] Occasional results are not inherent.

Civil Procedure > Appeals > Reviewability > Preservation for Review

[HN6] Appellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record.

Patent Law > Anticipation & Novelty > General Overview

[HN7] Where the result is a necessary consequence of what was deliberately intended, it is of no import that the reference article's authors did not appreciate the results.

COUNSEL: Jeffrey A. Schwab, Abelman, Frayne & Schwab, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Michael Aschen and Anthony J. DiFilippi. Of counsel on the brief was George A. Arkwright, Schlesinger, Arkwright & Garvey, LLP, of Arlington, Virginia.

Wayne L. Stoner, Hale and Dorr, LLP, of Boston, Massachusetts, argued for defendants-appellees. With him on the brief were William F. Lee and James M. Hall. Of counsel on the brief was Thomas A. Reed, Palomar Medical Technologies, Inc., of Lexington, Massachusetts.

JUDGES: Before MAYER, MICHEL, and RADER, Circuit Judges.

OPINIONBY: RADER

OPINION: [*1363]

RADER, Circuit Judge.

In this patent infringement action, MEHL/Biophile International Corp., Selvac Acquisitions Corp., and Dr. Nardo Zaias (collectively, MEHL/Biophile) asserted that Dr. Sandy Milgraum, Palomar Medical Technologies, Inc., and Spectrum Medical Technologies, Inc. (Milgraum) infringed U.S. Patent No. *5,059,192* (the *'192* patent). On its motion for summary judgment, Milgraum contended that all of the *'192* patent claims were anticipated [**2] by an instruction manual for the Spectrum RD-1200 laser and by a 1987 Journal of Investigative Dermatology article authored by Dr. Luigi Polla and others (the Polla article). The district court agreed that the manual anticipated the claims, granted summary judgment of invalidity, and dismissed the action. See MEHL/Biophile Int'l [*1364] *Corp. v. Milgraum, 8 F. Supp. 2d 434, 47 U.S.P.Q.2D (BNA) 1248 (D.N.J. 1998).* Although this court disagrees that the manual discloses all the elements of the claimed invention, because the Polla article does, this court affirms.

I.

The *'192* patent, entitled "Method of Hair Depilation," claims a method for removing hair using a laser. Hairs grows out of hair follicles, tubular apertures in the skin. The collection of germ cells from which hairs grow, known as the papilla, lies at the base of the follicle. The *'192* patent claims a method for destroying the papilla, thereby preventing hair regrowth. The written description discloses the use of a Q-switched ruby laser to effect the destruction.

At a meeting of the American Academy of Dermatology, Dr. Zaias visited Spectrum's booth where Spectrum displayed such a laser, known as the RD-1200. Spectrum sold [**3] the RD-1200 for use in removing tattoos. Dr. Zaias recognized that the same principles that govern laser absorption in skin pigmented by a tattoo would also focus laser absorption on the natural skin pigment found in the papilla. More specifically, the papilla contains granules (called melanosomes) of a dark pigment (called melanin). A Q-switched ruby laser aimed at the hair follicle will penetrate the skin and reach the papillary melanin. At a particular wavelength, the laser will heat up and destroy the papilla without damaging surrounding tissue.

Claim 1 of the patent, the only independent claim, reads:

> 1. A method of hair depilation, comprising the steps of:
>
> a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla;
>
> b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin [**4] is avoided.

Dependent claims 2-6 further specify parameters of the laser light applicator, energy delivery, and the type of laser.

MEHL/Biophile sued Milgraum in the United States District Court for the District of New Jersey for infringement of all the claims of the *'192* patent. Milgraum moved for summary judgment of invalidity based on *35 U.S.C. § 102* (1994), arguing that two prior art references each teach all the limitations of the claims. As noted at the outset, Milgraum relied on the manual for the RD-1200 laser which describes the use of a laser to remove tattoos. The manual teaches the use of a Q-switched ruby laser to remove a tattoo: "Energy is selectively absorbed only by pigmented chromophores and not surrounding tissue, greatly reducing the risk of scarring."

Milgraum also relied on the Polla article entitled "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin." The Polla article documents "the tissue damage induced by Q-switched ruby laser pulses in black, brown, and albino (control) guinea pigs . . . in an effort to define the nature and extent of pigmented cell injury." The method involves epilating [**5] guinea pigs with soft wax, holding the aperture of the laser in contact with the skin, and pulsing the laser. Using an electron microscope, the researchers observed "disruption of melanosomes deep in the hair papillae."

The district court considered both references, but ultimately rested its decision on the RD-1200 manual. MEHL/Biophile appeals. MEHL/Biophile makes several arguments for disregarding the manual as an anticipating reference. For instance, MEHL/Biophile argues that the manual does not teach use of the laser to remove hair at all. Further MEHL/Biophile contends that the manual does not disclose a substantially vertical alignment, a claim element. As for the Polla article, [*1365] MEHL/Biophile argues that the reference relates to guinea pig skin and does not mention hair depilation. In addition, MEHL/Biophile contends that the epilation of the guinea pig backs removed the papilla so the laser treatment could not have damaged the papilla.

II.

[HN1] This court reviews a district court's grant of summary judgment by reapplying the standard applicable at the district court. See *Conroy v. Reebok Int'l, Ltd., 14 F.3d 1570, 1575, 29 U.S.P.Q.2D (BNA) 1373, 1377 (Fed. Cir. 1994)*. [HN2] Summary [**6] judgment is appropriate only when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*. In its review, this court draws all reasonable inferences in favor of the non-movant. See *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)*.

[HN3] "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D (BNA) 1429, 1431 (Fed. Cir. 1997)*. As this court's predecessor stated in *In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (CCPA 1981)* (quoting *Hansgirg v. Kemmer, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 U.S.P.Q. (BNA) 665, 667 (CCPA 1939))* (internal citations omitted):

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance [**7] of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Thus, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *In re Oelrich, 666 F.2d at 581; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987)*. [HN4] Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King, 801 F.2d 1324, 1326, 231*

U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id., 801 F.2d at 1326.*

The RD-1200 Manual

The RD-1200 manual cannot anticipate because it does not teach all the limitations of the claimed invention. Claim 1 includes the step of "aligning a laser light applicator substantially vertically over a hair follicle opening." The parties agree [**8] that the manual does not discuss hair follicles, let alone aligning the laser over a hair follicle opening. Thus, the manual does not explicitly teach alignment substantially vertically over a follicle opening. Without explicit teachings of this claim limitation, this court must nonetheless examine whether such alignment is inherent in the manual's disclosure.

The manual teaches aiming the laser at skin pigmented with tattoo ink. The record discloses no necessary relationship between the location of a tattoo and the location of hair follicles. Therefore, an operator of the RD-1200 laser could use the laser according to the manual without necessarily aligning the laser "substantially vertically over a hair follicle opening." The possibility of such an alignment does not legally suffice to show anticipation. See *In re Oelrich, 666 F.2d at 581.* [HN5] Occasional results are not inherent. Because this court holds that the manual does not inherently teach this limitation of the claimed invention, it does not address MEHL/Biophile's other arguments. To anticipate, a single reference must teach every limitation of the claimed invention. Without an inherent teaching about alignment, [**9] the manual does not anticipate the claimed invention.

[*1366] The Polla Article

Although the district court did not reach the Polla article in its anticipation analysis, [HN6] "appellees always have the right to assert alternative grounds for affirming the judgment that are supported by the record." *Datascope Corp. v. SMEC, Inc., 879 F.2d 820, 822 n.1, 11 U.S.P.Q.2D (BNA) 1321, 1322 n.1 (Fed. Cir. 1989).* Milgraum asserts that the Polla article constitutes such an alternative ground. This court agrees.

As to the "aligning" step, the Polla article does not suffer from the same deficiency as the manual. It is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle. The researchers focused their study on the epilated backs of guinea pigs. No one disputes that guinea pigs have hairy backs. Indeed, the article itself is replete with references to the irradiation of hair follicles and resulting follicular damage:

> At 0.8 J/cm2, epidermal lesions were more marked and involved hair follicles 0.3 mm below the skin surface . . . . Lesions were also present 0.5 mm deep in follicles. [**10]
>
> Even at the highest radiant exposure (1.2 J/cm2), brown [guinea pig] skin never showed full-thickness epidermalnecrosis and at 0.8 J/cm2, follicular damage was observed to a depth of 0.5 mm and at 1.2 J/cm2 to a depth of 0.7 mm below the skin surface.
>
> . . . .
>
> Follicular changes were similar in nature and extent to the epidermal alterations described above, and were associated with melanosome disruption.
>
> . . . .
>
> Specifically, we have shown that . . . pigmented structures in the deep dermis such as hair follicles are affected . . . .

The article further contains a photograph showing "follicular changes induced by ruby laser." The changes include disruption of "melanosomes contained within follicular epithelium." Moreover the article specifically mentioned disruption of the hair papillae:

> At 0.8 and 1.2 J/cm2, individual melanosomes were more intensely damaged and disruption of melanosomes deep in the hair papillae was observed.

Finally, the method of exposing the Q-switched ruby laser to the guinea pig skin also inherently teaches substantially vertical alignment over hair follicle openings:

> The collimated laser beam struck a circular [**11] aperture, 2.5 mm in diameter, held in contact with the skin of the animals.

The record shows that holding the collimated laser in contact with the skin would align it perpendicular to the

skin surface and therefore substantially vertically over follicle openings. Viewed as a whole, this disclosure shows, in the words of *In re Oelrich, 666 F.2d at 581,* that the "natural result flowing from the operation as taught would result in" alignment of the laser light over a hair follicle, as claimed. No reasonable jury could find otherwise.

MEHL/Biophile's remaining arguments concerning the Polla article are unavailing. The Polla article concerns itself with guinea pig, rather than human, skin, but that difference is irrelevant to the anticipation analysis. Nothing in the claim limits the method's reach to human skin. Similarly, the Polla article's failure to mention hair depilation as a goal is similarly irrelevant. MEHL/Biophile does not dispute on appeal that the laser operating parameters disclosed in the article substantially coincide with those disclosed in the patent. Accordingly, to the extent the embodiment in the patent achieves hair depilation, so does the [**12] Polla method. [HN7] Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results. See *W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1548, 220 U.S.P.Q. (BNA) 303, 309 (Fed. Cir. 1983).* Finally, as mentioned earlier, the article itself belies MEHL/Biophile's argument that the wax epilation prescribed by the article resulted in removal of the papilla. [*1367] The article specifically states that "disruption of melanosomes deep in the hair papillae was observed." MEHL/Biophile's expert testimony contradicting the plain language of the reference does not create a genuine issue of fact.

Thus, the Polla article anticipates claim 1 of the *'192* patent. Because MEHL/Biophile has not separately argued the validity of the dependent claims, the judgment of invalidity as to those claims also stands.

COSTS

Each party shall bear its own costs.

AFFIRMED

Exhibit E

Trintec Ind. Inc. v. Top USA, 295 F.3d 1292 (Fed. Cir. 2002)

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

LEXSEE 63 USPQ 2D 1597

TRINTEC INDUSTRIES, INC., Plaintiff-Appellant, v. TOP-U.S.A. CORPORATION, Defendant-Appellee.

01-1568

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

295 F.3d 1292; 2002 U.S. App. LEXIS 13190; 63 U.S.P.Q.2D (BNA) 1597

July 2, 2002, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Southern District of Ohio Senior Judge Joseph P. Kinneary.

DISPOSITION: Vacated and remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent assignee sued defendant company alleging infringement. The United States District Court for the Southern District of Ohio granted summary judgment in favor of the company on the grounds the patent was invalid as inherently anticipated. The patent assignee appealed.

OVERVIEW: The patent claimed a cost-effective method of producing, in low volume, multicolor faces for watches, clocks, thermometers and other instruments. The method included making a graphic instrument face in a computer, transmitting electronic signals from the computer to a color printer or photocopier, printing the face on sheet material, cutting it, and assembling it into an instrument. The company produced watches and clocks with customized faces. The company used color laser printers to make custom watches and clocks. A different manufacturer also was in the business of customized watches and advertised in a catalogue the availability at an inexpensive price of small-volume multi-color watches produced by a new computer laser printer. The district court found that the catalogue inherently anticipated the asserted claims and granted summary judgment of invalidity. The court of appeals held that given the strict identity required of the test for novelty, on the record no reasonable jury could conclude that the catalogue anticipated either expressly or inherently the claim at issue. Because the record was not fully developed the issue of obviousness could not be reached.

OUTCOME: The judgment was vacated and the matter was remanded for a determination on the issue of obviousness and other proceedings consistent with the opinion.

LexisNexis(R) Headnotes

Patent Law > Infringement Actions > Summary Judgment > Appeals
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Anticipation & Novelty > Fact & Law Issues
[HN1] Under patent law, an appeals court reviews a district court's grant of summary judgment without deference. An appeals court also reviews without deference questions of claim construction. Novelty, or anticipation, is a question of fact. Therefore, a district court properly may grant summary judgment on an identity question only when the record discloses no genuine material factual issues.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Infringement Actions > Claim Interpretation > Aids
Patent Law > Infringement Actions > Claim Interpretation > Construction Preferences
[HN2] Under patent law with regard to a claim of infringement, because novelty's identity requirement applies to claims, not specifications the anticipation inquiry first demands a proper claim construction. Claim

language defines claim scope. As a general rule, claim language carries the ordinary meaning of the words in their normal usage in the field of invention. Nevertheless, the inventor may act as his own lexicographer and use the specification to supply implicitly or explicitly new meanings for terms. Thus, a construing court may consult as well the written description, and, if in evidence, the prosecution history.

Patent Law > Anticipation & Novelty > Accidental Anticipation & Inherency
Patent Law > Anticipation & Novelty > Elements
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN3] Under patent law, a single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim. Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art.

Patent Law > Anticipation & Novelty > Accidental Anticipation & Inherency
Patent Law > Anticipation & Novelty > Elements
[HN4] Under patent law, obviousness is not inherent anticipation. Though anticipation is the epitome of obviousness, they are separate and distinct concepts.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN5] Under patent law, obviousness involves questions of suggestion to combine and objective indicators of patentability.

COUNSEL: Robert A. Vanderhye, Nixon & Vanderhye P.C., of Arlington, Virginia, argued for plaintiff-appellant.

David P. Shouvlin, Porter, Wright, Morris, & Arthur, LLP, of Columbus, Ohio, argued for defendant-appellee. On the brief was David W. Costello. Of counsel was Richard M. Mescher.

JUDGES: Before MAYER, Chief Judge, RADER, and GAJARSA Circuit Judges.

OPINIONBY: RADER

OPINION: [*1293] Before MAYER, Chief Judge, RADER, and GAJARSA Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the Southern District of Ohio found Trintec Industries, Inc.'s United States Patent No. *5,818,717* (*'717* patent) invalid as inherently anticipated. Trintec, Indus. v. Top-U.S.A. Corp., No. C-2-99-1179 (S.D. Ohio Jun. 19, 2001). Because the *'717* patent is not inherently anticipated, this court vacates and remands.

I.

Trintec is the assignee of the *'717* patent. The inventor, Brendon G. Nunes, [*1294] filed the *'717* patent application on June 2, 1993. The *'717* patent claims a cost-effective method of producing, in low volume, multicolor faces for watches, clocks, [**2] thermometers and other instruments. The method includes making a graphic instrument face in a computer, transmitting electronic signals from the computer to a color printer or photocopier, printing the face on sheet material, cutting it, and assembling it into an instrument.

Top-U.S.A. Corporation produces watches and clocks with customized faces, and has done so for over eighteen years. Initially, Top created and printed its customized graphics using pad printing, engraving, silk screening, or photography. Those methods were expensive and required extensive set-up time. Thus, these older methods were ill-suited to small-volume custom design and printing. Desktop publishing's advent in the late 1980s mitigated the design side of this problem, but high-resolution color printing remained prohibitively expensive. With color laser printer advances, however, Top was using that technology to make custom watches and clocks by 1995.

Sweda Company LLC also is in the customized watch business. In a 1991-92 catalogue (Sweda catalogue), Sweda advertised the availability at an inexpensive price of small-volume multi-color watches produced by "a new computer laser printer." The Sweda catalogue [**3] was not before the examiner of the *'717* patent during its prosecution.

On November 2, 1999, Trintec asserted the *'717* patent against Top in the district court. Trintec alleged that Top infringed independent claims 3 and 8, and associated dependent claims 4-5, 12, and 13. Trintec filed a motion for summary judgment of infringement, intentional infringement, and validity. Top filed a cross-motion for summary judgment that the asserted claims either were anticipated or obvious in view of the Sweda catalogue. The district court found that the Sweda catalogue inherently anticipated the asserted claims and granted summary judgment of invalidity. Having determined that prior art anticipated the *'717* patent, the district court did not reach obviousness and dismissed the case with prejudice. Trintec appeals the district court's summary judgment of invalidity. This court has jurisdiction under *28 U.S.C. § 1295*(a)(1) (2000).

II.

[HN1] This court reviews a district court's grant of summary judgment without deference. *Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353, 47 U.S.P.Q.2D (BNA) 1705, 1713 (Fed. Cir. 1998).* This court also reviews without deference questions [**4] of claim construction. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 U.S.P.Q.2D (BNA) 1169, 1174 (Fed. Cir. 1998)* (en banc). Novelty, or anticipation, is a question of fact. *Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1 U.S.P.Q.2D (BNA) 1241 (Fed. Cir. 1986).* Therefore, a district court properly may grant summary judgment on this identity question only when the record discloses no genuine material factual issues.

[HN2] Because novelty's identity requirement applies to claims, not specifications, *Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 7 U.S.P.Q.2D (BNA) 1057, 1064 (Fed. Cir. 1988),* the anticipation inquiry first demands a proper claim construction. Claim language defines claim scope. *SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121, 227 U.S.P.Q. (BNA) 577, 586 (Fed. Cir. 1985)* (en banc). As a general rule, claim language carries the ordinary meaning of the words in their normal usage in the field of invention. *Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1299, 53 U.S.P.Q.2D (BNA) 1065, 1067 (Fed. Cir. 1999).* Nevertheless, [*1295] the inventor may act as his own lexicographer and use the specification [**5] to supply implicitly or explicitly new meanings for terms. *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-80, 34 U.S.P.Q.2D (BNA) 1321, 1330 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).* Thus, a construing court may consult as well the written description, and, if in evidence, the prosecution history. Id.

[HN3] A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim. *Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987).* Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art. *In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2D (BNA) 1949, 1950-51 (Fed. Cir. 1999)* (citing *Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991)).*

In this case, the district court determined that the Sweda catalogue anticipated, or disclosed and enabled each and every element of, the claimed invention. [**6] The Sweda catalogue advertises three different methods of making customized watches: a "full color watch rendering" method, a "mock-up sample" method, and a "speculative sample" method. The catalogue states that the first two methods use a computer laser printer, and the "speculative samples" method uses silk-screening, hot stamping, color process/offset printing, etchograph stamping, or engraving. The catalogue then shows images of color watch faces made with each of the advertised methods. All three methods require the customer to submit "camera ready, color separated artwork," i.e., separate pieces of black and white artwork representing each color in the design.

Top concedes that the Sweda catalogue does not teach expressly all limitations of the asserted claims. Hence, the only issue for this court to determine is whether the claim limitations not taught expressly by the Sweda catalogue are nevertheless disclosed inherently. This inherent anticipation question implicates claims 3 and 8. Claim 3 recites, in relevant part:

> 3. A method of constructing a functional multicolor element having indicia thereon, utilizing a computer and a color photocopier, comprising the steps [**7] of:
>
> (a) electronically creating or providing in the computer an electronic simulation of the desired functional multicolor element, with indicia thereon;
>
> (b) under the control of the computer, transmitting electronic signals from the computer to the photocopier so that the photocopier transforms the electronic simulation of the desired functional multicolor element onto a piece of sheet material . . . .

Col. 7, ll. 16-26 (emphases added).

The district court construed the term "color photocopier" to mean a "color printer." The district court noted that the Sweda catalogue expressly advertises: "A color picture of your customers custom logo produced by our new advanced computer laser printer." Based on this, the district court determined that the Sweda catalogue inherently disclosed a color printer because "those in the graphic arts industry would have recognized that a color printing device is necessarily present in the catalogue's description of 'a full color rendering' produced from a 'computer laser printer.'" Nevertheless, a color printer is not a color photocopier.

The *'717* patent specification teaches that a "major component" of the invention [*1296] "is a printer, [**8] preferably a color photocopier." Col. 3, ll. 62-64. At the same time, the patent also recognizes that a color

photocopier does more than print in color -- it copies. Specifically, the specification teaches "photocopying with a color photocopier, such as of the types earlier described." Col. 6, ll. 20-21. The undisputed trial testimony of Dr. Steven J. Bares underscores this point: "Digital color copiers comprise a digital color scanner and a digital color laser printer which are directly connected together so that graphics transformed into digital information through the scanner are transmitted to the digital color laser printer for printing." As a matter of correct claim construction, therefore, a "color photocopier" requires the ability both to print and photocopy subject matter with color.

The difference between a printer and a photocopier may be minimal and obvious to those of skill in this art. Nevertheless, [HN4] obviousness is not inherent anticipation. *Jones v. Hardy, 727 F.2d 1524, 1529, 220 U.S.P.Q. (BNA) 1021, 1025 (Fed. Cir. 1984)* ("though anticipation is the epitome of obviousness, [they] are separate and distinct concepts"). Given the strict identity required of the [**9] test for novelty, on this record no reasonable jury could conclude that the Sweda catalogue discloses either expressly or inherently a color photocopier. Because claim 3 is not inherently anticipated, dependent claims 4 and 5 also are not anticipated.

Claim 8 recites, in relevant part:

> 8. A method of producing an instrument face having functional indicia thereon, utilizing a computer and printer, comprising the steps of:
>
> (a) creating the instrument face with functional indicia thereon in the computer in electronic format . . . .

Col. 8, ll. 1-5 (emphases added). While claim 3 has the broader language "creating or providing," claim 8 recites only "creating." Nonetheless, the district court interpreted both claims to require "creating or providing in a computer a multicolor logo and hour markings to comprise the face of an instrument." (Emphasis added.) The district court found that the Sweda catalogue inherently anticipated "creating or providing" as required by its claim construction. Because claim 8 requires "creating" rather than "creating or providing," the district court erred in its construction of that claim and in its corresponding determination [**10] of inherent anticipation.

The *'717* patent does not define expressly "creating" or "providing." The two terms, however, have distinct meanings. Each term appears in claim language. Each therefore imparts a different scope to the claim in which it appears. See, e.g., *Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562, 19 U.S.P.Q.2D (BNA) 1500, 1503 (Fed. Cir. 1991)* ("The fact that mitered linear border pieces meet to form a right angle corner does not make them right angle corner pieces, when the claim separately recites both linear border pieces and right angle corner border pieces.").

In its teachings, the specification treats the two terms differently. For example, with respect to preparing an instrument face for printing, the specification describes a two step process: "The artwork . . . is created in electronic format in the computer. Information may initially be inputted into the computer for this purpose from a conventional scanner or a CD ROM." Col. 4, ll. 7-11 (emphasis added). In sum, the patent recognizes that information may be provided (input) into the computer after creation elsewhere or, alternatively, may be created in the computer from scratch. Regarding [**11] the creating step, the specification further teaches that "commercially available software programs" may be used to "produce almost [*1297] any design desired on an instrument face." Col. 4, ll. 11-14, 18. In view of these teachings, this court construes "creating" to require more than simply using the computer as a conduit to convey information to the printer from a scanner or a CD ROM. Creating requires, rather, a substantive addition or modification of the artwork in the computer, such as when graphics software adds a design to an instrument face.

The Sweda catalogue discloses, as discussed above, various printing methods. These printing methods disclose nothing about creating artwork in a computer. For this reason, the Sweda catalogue does not inherently anticipate claim 8. Specifically, the Sweda catalogue may well have created instrument faces with conventional manual methods. Then after manual creation or assembly, the Sweda catalogue may have provided those faces to a computer only for printing. Indeed, the Sweda catalogue required expressly that its customers provide color separations of their artwork. The record suggests that those of skill in this art use color separations to create [**12] manually a composite color rendering of the desired image. Then a black and white laser printer makes separate transparent color sheets based on the color separations. Finally, the artisans overlay the separate color sheets manually to form a composite color rendering of the desired image. This process requires no substantive addition or modification of the artwork in the computer -- as mandated by a correct reading of the term "create." In other words, the process suggested by the Sweda catalogue combines the color sheets outside of the computer, with the computer serving merely as a conduit for printing. It is irrelevant that a skilled artisan might possibly use the computer to

create the final desired image from the color separations. Inherency does not embrace probabilities or possibilities. *In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2D (BNA) 1949, 1951 (Fed. Cir. 1999).* In sum, no reasonable jury could find that the Sweda catalogue anticipates either expressly or inherently this claim.

Cases involving novelty, with its strict identity requirement, are quite rare. Obviousness seems the actual issue here. This court, however, cannot reach that question without a fully [**13] developed record. [HN5] Obviousness involves, for instance, questions of suggestion to combine, see, e.g., *In re Rouffet, 149 F.3d 1350, 47 U.S.P.Q.2D (BNA) 1453 (Fed. Cir. 1998),* and objective indicators of patentability, see, e.g., *Graham v. John Deere Co., 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).* On appeal, this court cannot venture into these factual and complex areas without a developed record. Accordingly, this record requires remand to permit the trial court to apply the obviousness standards in light of the Sweda catalogue and other prior art as viewed with the knowledge of one of skill in the art at the time of invention.

CONCLUSION

Because the district court erred in granting summary judgment that claims 3-5, 8, 12, and 13 are inherently anticipated, this court vacates and remands for a determination on the issue of obviousness and other proceedings consistent with this opinion.

COSTS

Each party shall bear its own costs.

VACATED AND REMANDED

Exhibit F

Rosco Inc. v. Mirror Lite Co., 304 F.3d 1373 (Fed. Cir. 2002)

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

LEXSEE 64 USPQ 2D 1676

ROSCO, INC., Plaintiff-Appellant, v. MIRROR LITE COMPANY, Defendant-Cross Appellant.

01-1271, 01-1302

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

304 F.3d 1373; 2002 U.S. App. LEXIS 20206; 64 U.S.P.Q.2D (BNA) 1676

September 24, 2002, Decided

SUBSEQUENT HISTORY: [**1] Rehearing and Rehearing En Banc Denied December 5, 2002, Reported at: *2002 U.S. App. LEXIS 27299.* Rehearing denied by, Rehearing, en banc, denied by *Rosco, Inc. v. Mirror Lite Co., 2002 U.S. App. LEXIS 27299* (Fed. Cir., Dec. 5, 2002)
On remand at, Findings of fact/conclusions of law at *Rosco, Inc. v. Mirror Lite Co., 2003 U.S. Dist. LEXIS 26209* (E.D.N.Y., July 8, 2003)

PRIOR HISTORY: Appealed from: United States District Court for the Eastern District of New York. Senior Judge Charles P. Sifton. *Rosco, Inc. v. Mirror Lite Co., 139 F. Supp. 2d 287, 2001 U.S. Dist. LEXIS 871* (E.D.N.Y., 2001)

DISPOSITION: AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant manufacturer sued appellee/cross-appellant company for patent infringement, tortious interference with business relations, misrepresentation, and common law trademark infringement. The United States District Court for the Eastern District of New York ruled for the company on all claims. The manufacturer appealed.

OVERVIEW: The manufacturer claimed that the company infringed on the manufacturer's convex cross-view mirror with a black, flat metal backing for school buses. The appellate court held that the mere fact that the manufacturer's mirror claimed in the design patent exhibited a superior field of view over a single predecessor mirror did not establish that the design was dictated by functional considerations. Other mirrors that had non-oval shapes also offered that particular field of view. Nothing in the record connected the oval shape of the patented design with aerodynamics. Further, other non-oval shaped mirrors had the same aerodynamic effect. The company had not shown by clear and convincing evidence that there were no designs, other than the one shown in the manufacturer's patent, that had the same functional capabilities as the manufacturer's oval mirror. Under these circumstances, it could not have been said that the claimed design of the mirror patent was dictated by functional considerations. Finally, there was no evidence that one skilled in the art would read the patent as inherently disclosing a mirror with varying radius of curvature along the major axis.

OUTCOME: The appellate court reversed the district court's: (1) ruling that the mirror patent claim was invalid on functionality grounds; (2) finding of invalidity of the utility patent; finding that the utility patent was invalid under anticipation; finding that the utility patent was unenforceable for inequitable conduct. The appellate court remanded the tortious interference claim, and affirmed the denial of the misrepresentation and trademark claims.

LexisNexis(R) Headnotes

Civil Procedure > Trials > Bench Trials
[HN1] *Fed. R Civ. P. 52(a)* requires that in all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon. *Fed. R. Civ. P. 52(a).* A trial court must provide sufficient factual

findings such an appellate court may meaningfully review the merits of its order.

Evidence > Procedural Considerations > Inferences & Presumptions
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
[HN2] A patent shall be presumed valid. *35 U.S.C.S. § 282.* To overcome this presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence.

Patent Law > Subject Matter > Designs > Ornamentality Requirement
Patent Law > Subject Matter > Designs > Functionality
Patent Law > Inequitable Conduct > Burdens of Proof
[HN3] Courts apply a stringent standard for invalidating a design patent on grounds of functionality: the design of a useful article is deemed functional where the appearance of the claimed design is dictated by the use or purpose of the article. The design must not be governed solely by function, i.e., that this is not the only possible form of the article that could perform its function. When there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose. That is, if other designs could produce the same or similar functional capabilities, the design of the article in question is likely ornamental, not functional. Invalidity of a design patent claim must be established by clear and convincing evidence.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Nonobviousness > Evidence & Procedure > Presumptions & Proof
[HN4] In a patent case, a finding of obviousness cannot be made without determining whether the invalidating prior art shows or renders obvious the ornamental features of the claimed design.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN5] In a patent case, the obviousness of a design is determined by ascertaining whether the applicable prior art contains any suggestion or motivation for making the modifications in the design of the prior art article in order to produce the claimed design. The inquiry under *35 U.S.C.S. § 103* is whether the claimed design would have been obvious to a designer of ordinary skill who designs articles of the type involved.

Patent Law > Anticipation & Novelty > Accidental Anticipation & Inherency
Patent Law > Anticipation & Novelty > Elements
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN6] In a patent case, under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art.

Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Anticipation & Novelty > Invention
Patent Law > Infringement Actions > Defenses > Patent Invalidity > General Overview
[HN7] A patent is invalid under *35 U.S.C.S. § 102*(g)(2) if, before the applicant's invention thereof, the invention was made in the United State by another who had not abandoned, suppressed, or concealed it. *35 U.S.C.S. § 102*(g)(2). Prior invention by another invalidates a claimed invention under § 102(g)(2) if the prior inventor either reduced the invention to practice first, or conceived of the invention first and subsequently reduced the invention to practice. However, conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention. There is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the invention.

Patent Law > Date of Invention & Priority > General Overview
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Defenses > Patent Invalidity > General Overview
[HN8] In a patent case, a party claiming his own prior inventorship must proffer evidence corroborating his testimony.

Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview
Trademark Law > Federal Unfair Competition Law > False Designation of Origin > Elements

Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview

[HN9] To establish misrepresentation under *15 U.S.C.S. § 1125*(a), a plaintiff must show that the statement at issue is either: (1) literally false as a factual matter; or (2) although literally true, it is likely to deceive or confuse customers. The plaintiff must also prove that the defendant misrepresented an inherent quality or characteristic of the product.

Trademark Law > Infringement Actions > General Overview

Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview

Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview

[HN10] *15 U.S.C.S. § 1125*(a) protects unregistered marks.

Trademark Law > Infringement Actions > Burdens of Proof

Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > Causes of Actions

Trademark Law > Federal Unfair Competition Law > False Designation of Origin > Elements

[HN11] Unregistered marks receive essentially the same protection as registered marks. Courts interpret § 43(a) of the Lanham Act, *35 U.S.C.S. § 1125*(a) as having created a federal cause of action for infringement of unregistered trademark or trade dress and concludes that such a mark or trade dress should receive essentially the same protection as those that are registered. When § 43(a) of the Act is used as a federal vehicle for assertion of traditional claims of infringement of trademarks, the courts uses as substantive law the traditional rules of trademarks and unfair competition law. The test of liability is likelihood of confusion. Under § 43(a), the ultimate test is whether the public is likely to be deceived or confused by the similarity of the marks. Whether it is called the violation infringement, unfair competition, or false designation of origin, the test is identical--is there a likelihood of confusion? To prevail on a claim for common law trademark infringement under *35 U.S.C.S. § 1125*(a), a party must show likelihood of confusion. This is required by the statute itself: § 1125(a) is triggered by a use that is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association" of the user with the senior user.

COUNSEL: Alfred R. Fabricant, Ostrolenk, Faber, Gerb & Soffen, LLP, of New York, New York, argued for plaintiff-appellant. With him the brief was Max Moskowitz.

John A. Artz, Artz & Artz, P.C., of Southfield, Minnesota, argued for defendant-cross appellant. With him on the brief were John S. Artz and Robert P. Renke.

JUDGES: Before LOURIE, Circuit Judge, PLAGER, Senior Circuit Judge, and DYK, Circuit Judge.

OPINIONBY: DYK

OPINION: [*1376]

DYK, Circuit Judge.

Rosco, Inc. ("Rosco") appeals the decision of the United States District Court for the Eastern District of New York finding Rosco's design patent, United States Design Patent No. *346,357* ("the *'357* patent"), invalid as functional and obvious, finding that Rosco abandoned its claim that Mirror Lite Company ("Mirror Lite") inequitably procured its utility patent, United States Patent No. *5,589,984* ("the *'984* patent"), and rejecting Rosco's claims under *15 U.S.C. § 1125*(a) of tortious interference with business relations, misrepresentation, [**2] and common law trademark infringement. *Rosco, Inc. v. Mirror Lite Co., 139 F. Supp. 2d 287 (E.D.N.Y. 2001).* Mirror Lite cross-appeals the district court's decision that the claims of the *'984* patent are invalid. Because the district court erred in finding the *'357* patent invalid as functional and obvious; finding the claims of the *'984* patent invalid under *35 U.S.C. § § 102*(e) and 102(g); and finding that Rosco abandoned its inequitable conduct claims, we reverse in part, vacate in part, and remand. On remand, the district court should make findings and conclusions on all relevant issues as required by *Federal Rule of Civil Procedure 52. Fed. R. Civ. P. 52.* We affirm the district court's rejection of Rosco's claims under *15 U.S.C. § 1125*(a) of misrepresentation and common law trademark infringement.

BACKGROUND

Rosco and Mirror Lite are competitors in the school bus mirror market. This dispute involves "cross-view" mirrors, which are convex, three-dimensional, curved surface mirrors mounted on the front fender of a school bus, enabling the bus driver to view the front and passenger side of a school bus. Rosco filed a complaint [**3] on November 19, 1996, and amended the complaint on December 27, 1996 (the "Rosco I case"). A second civil action was subsequently filed by Rosco in October 1999 (the "Rosco II case"). Mirror Lite asserted a counterclaim in the second action. The two cases were consolidated.

Each party owns a patent that it alleged was infringed by the other. Rosco raised a variety of other claims.

1. Rosco's *'357* Design Patent

Rosco's *'357* design patent relates to an oval, highly convex cross-view mirror with a black, flat metal backing. Rosco applied for the patent on April 14, 1992, and the patent issued on April 26, 1994. Rosco alleged that Mirror Lite infringed the *'357* design patent. Mirror Lite argued that the *'357* design patent was invalid as functional and therefore was not infringed.

2. Mirror Lite's *'984* Utility Patent

Mirror Lite's *'984* utility patent relates to an oval cross-view mirror with a varying radius of curvature along the major axis of the convex ellipsoid mirror lens. Mirror Lite filed the parent application that led to the *'984* patent on September 9, 1992. The '948 patent issued on December 31, 1996. Rosco requested declaratory judgment that all claims of the *'984* patent [**4] were invalid as anticipated under *35 U.S.C. § 102*(a), invalid for failure to name the true inventor under *35 U.S.C. § 102*(f), invalid as previously invented by another under *35 U.S.C. § 102*(g), and unenforceable due to Mirror Lite's inequitable conduct in procuring the patent. n1 Mirror Lite counterclaimed that Rosco infringed the *'984* patent.

n1 The district court deemed Rosco's complaint amended to add claims of patent invalidity under *35 U.S.C. § 102*(e) (inherently anticipated by prior art) and *35 U.S.C. § 103* (invalid as obvious). *Rosco, 139 F. Supp. 2d at 300.*

[*1377] 3. Rosco's Other Claims

Rosco also alleged that Mirror Lite: engaged in tortious interference with business relations by procuring the *'984* patent through inequitable conduct; engaged in misrepresentation by publishing disparaging statements about Rosco's mirrors; and engaged in common law trademark infringement by using [**5] the marks "Eagle Eye" and "Mini Eagle Eye" to compete with Rosco's "Hawk Eye" and "Mini Hawk Eye" products.

In the Rosco I case, Mirror Lite moved for summary judgment on all claims, and the district court granted summary judgment as to Rosco's claim of tortious interference with business relations. *Rosco, 139 F. Supp. 2d at 294-95.* The court denied Rosco's motion for reconsideration on August 19, 1999. Id. However, the court later effectively granted reconsideration and reinstated the claim of tortious interference with business relations. *Id. at 304 n.14.*

After a bench trial, the district court: found the *'357* design patent invalid as functional and obvious under *35 U.S.C. § 103;* found the claims of the *'984* patent invalid under *35 U.S.C. § § 102*(e) and 102(g); did not reach Rosco's claim for design patent infringement because it found the *'357* patent invalid; did not reach Mirror Lite's claim of patent infringement because it found the *'984* patent claims invalid; did not address the validity of the *'984* patent under *35 U.S.C. § § 102*(a), 102(f), and 103; found that Rosco abandoned [**6] its inequitable conduct claims; and rejected Rosco's claims of misrepresentation and common law trademark infringement.

The parties timely appealed. We have jurisdiction under *28 U.S.C. § 1295*(a)(1).

DISCUSSION

This case presents an example of the need for clear findings of fact and conclusions of law. [HN1] *Federal Rule of Civil Procedure 52(a)* requires that "in all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon." *Fed. R. Civ. P. 52(a).* We have noted the importance of compliance with these requirements, recognizing that one of the purposes of Rule 52(a) is to "provide the appellate court with an adequate basis for review." *Gechter v. Davidson, 116 F.3d 1454, 1458, 43 U.S.P.Q.2D (BNA) 1030, 1033 (Fed. Cir. 1997);* see also *Pretty Punch Shoppettes, Inc. v. Hauk, 844 F.2d 782, 784, 6 U.S.P.Q.2D (BNA) 1563, 1565 (Fed. Cir. 1988)* ("The trial court must provide sufficient factual findings such that we may meaningfully review the merits of its order."). Here, the district court failed in several instances to make sufficient findings of fact [**7] and conclusions of law to provide the necessary predicate for judicial review.

We note also that the parties in this case have made prolix, confusing, and contentious arguments, which no doubt made it particularly difficult for the district court to address the issues with clarity and precision. We trust that, on remand, counsel will provide the necessary assistance to the district court by appropriately narrowing the issues and coherently explaining their respective positions.

I Rosco's *'357* Design Patent

[HN2] "A patent shall be presumed valid." *35 U.S.C. § 282* (2000). To overcome this presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. *Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 1036, 59 U.S.P.Q.2D (BNA) 1139, 1142-*

43 (Fed. Cir. 2001), cert. denied, *534 U.S. 1172, 152 L. Ed. 2d 136,* [*1378] *122 S. Ct. 1196 (2002)* (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770 (Fed. Cir. 1984)).*

Rosco's *'357* design patent shows a highly convex, curved-surface, three-dimensional oval mirror with a black, flat metal [**8] backing. In May 1992, Rosco began manufacturing the mirror of the *'357* patent under the name "Eagle Eye."

Rosco alleged that Mirror Lite infringed the *'357* patent by manufacturing and selling a duplicate of Rosco's mirror under the name "Hawk Eye." Mirror Lite argued that the *'357* patent was invalid as functional. The district court found the *'357* design patent invalid as functional. *Rosco, 139 F. Supp. 2d at 296.*

[HN3] We apply a stringent standard for invalidating a design patent on grounds of functionality: the design of a useful article is deemed functional where "the appearance of the claimed design is 'dictated by' the use or purpose of the article." *L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1123, 25 U.S.P.Q.2D (BNA) 1913, 1917 (Fed. Cir. 1993)* (citing *In re Carletti, 51 C.C.P.A. 1094, 328 F.2d 1020, 1022, 140 U.S.P.Q. (BNA) 653, 654 (CCPA 1964)).* "The design must not be governed solely by function, i.e., that this is not the only possible form of the article that could perform its function." *Seiko Epson Corp. v. Nu-Kote Int'l, Inc., 190 F.3d 1360, 1368, 52 U.S.P.Q.2D (BNA) 1011, 1017 (Fed. Cir. 1999).* "When there are several [**9] ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose." *L.A. Gear, 988 F.2d at 1123, 25 U.S.P.Q.2D at 1917* (citations omitted). That is, if other designs could produce the same or similar functional capabilities, the design of the article in question is likely ornamental, not functional. Invalidity of a design patent claim must be established by clear and convincing evidence. Id.

The district court found that because the mirror's oval shape, the asserted point of novelty of the *'357* patent, "of necessity dictates its function," the *'357* patent was invalid as functional. n2 *Rosco, 139 F. Supp. 2d at 296.* The court based its determination of functionality on its findings that the mirror of the *'357* patent offered a unique field of view (when compared to Mirror Lite's Bus Boy mirror); that Rosco represented to the Patent and Trademark Office that its mirror provided a superb field of view; and that Rosco marketed the mirror of the *'357* patent as more "aerodynamic" than other cross-view mirrors. Id.

n2 The district court's finding in this respect appears to be inconsistent with its earlier summary judgment decision, in which it noted: "A review of the other cross-over mirrors on the market reveals that several different styles of cross-over mirrors exist . . . . It cannot be said that the oval shape and flat backing are dictated by function." Rosco, Inc. v. Mirror Lite Co., No. CV-96-5658, at 15 (E.D.N.Y. June 2, 1999) (order granting summary judgment in part).

----------End Footnotes----------

[**10]

The mere fact that the invention claimed in the design patent exhibited a superior field of view over a single predecessor mirror (here, the Bus Boy) does not establish that the design was "dictated by" functional considerations, as required by L.A. Gear. The record indeed reflects that other mirrors that have non-oval shapes also offer that particular field of view. Similarly, nothing in the record connects the oval shape of the patented design with aerodynamics, and the record shows that other non-oval shaped mirrors have the same aerodynamic effect.

Mirror Lite has not shown by clear and convincing evidence that there are no designs, other than the one shown in Rosco's [*1379] *'357* patent, that have the same functional capabilities as Rosco's oval mirror. Under these circumstances it cannot be said that the claimed design of the *'357* patent was dictated by functional considerations. We reverse the district court and hold that the *'357* patent claim was not shown to be invalid on functionality grounds.

The district court in a footnote further found the *'357* patent claim invalid as obvious, stating simply that "the *'357* Patent is invalid as obvious." *Rosco, 139 F. Supp. 2d at 296 n.5.* [**11] No findings to support this holding of obviousness were made. [HN4] A finding of obviousness cannot be made without determining whether the invalidating prior art shows or renders obvious the ornamental features of the claimed design. *OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1404, 43 U.S.P.Q.2D (BNA) 1641, 1646 (Fed. Cir. 1997).* n3 Because the district court failed to make the necessary findings as to obviousness, we remand for compliance with Rule 52. Should the district court find the *'357* patent not invalid, the issue of whether that patent was infringed would have to be addressed by the district court.

n3 See *In re Haruna, 249 F.3d 1327, 1335, 58 U.S.P.Q.2D (BNA) 1517, 1522 (Fed. Cir.*

2001) [HN5] ("The obviousness of a design 'is determined by ascertaining whether the applicable prior art contains any suggestion or motivation for making the modifications in the design of the prior art article in order to produce the claimed design.'") (quoting *Hupp v. Siroflex of Am., Inc.,122 F.3d 1456, 1462, 43 U.S.P.Q.2D (BNA) 1887, 1891 (Fed. Cir. 1997)); Durling v. Spectrum Furniture Co., 101 F.3d 100, 103, 40 U.S.P.Q.2D (BNA) 1788, 1790 (Fed. Cir. 1996)* (The inquiry under section 103 is "whether the claimed design would have been obvious to a designer of ordinary skill who designs articles of the type involved.").

[**12]

II Mirror Lite's *'984* Utility Patent

Mirror Lite's *'984* patent claims an oval cross-view mirror with a varying radius of curvature along the major axis of the lens. Rosco sought a declaratory judgment that the *'984* patent claims were invalid under *35 U.S.C. § § 102* and 103, and that the *'984* patent was unenforceable on grounds of inequitable conduct.

The district court found claims 1-3 and 6-8 of the *'984* patent invalid under both *35 U.S.C. § 102*(e) (invalidating claims based on anticipation by an earlier filed United States application) and *35 U.S.C. § 102*(g) (invalidating claims based on prior invention "by another"). *Rosco, 139 F. Supp. 2d at 302-03.* Independent claim 1 provides:

> A mirror assembly, comprising:
>
> (a) a mirror lens having a reflective outer surface and a non-reflective rear surface, the mirror lens comprising a mirror body which terminates in an oval perimetral edge, the edge surrounds the reflective surface and the non-reflective surface of the mirror lens, the mirror body being a substantially convex ellipsoid having a major axis and a minor axis which intersects with [**13] the major axis, the major axis having a varying radius of curvature, which radius decreases from the intersection with the minor axis to the perimetral edge.

'984 patent, col. 4, ll. 21-31 (emphasis added). Claim 1 thus requires a "varying radius of curvature" along the major axis of the lens. Rosco argued that if the prior art disclosed the varying radius of curvature, then claim 1 is invalid. It made the same argument with respect to dependent claims 2-3 and 6-8. The district court agreed. *Rosco, 139 F. Supp. 2d at 302.*

When determining the validity of the claims of a patent, each claim must be separately considered:

> [*1380] Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting invalidity.

35 U.S.C. § 282 (2000) (emphasis added). Here, the district court found claims 1-3 and 6-8 of the *'984* patent [**14] invalid without explicitly addressing and analyzing each claim, apparently addressing only independent claim 1. n4 There is no evidence that Mirror Lite conceded that those claims stand or fall with independent claim 1. The district court erred by not separately addressing each claim, and on remand should do so. Because we find that the district court's grounds for finding invalidity are not substantiated, we need not consider the claims individually here.

> n4 Also, the district court failed to explicitly mention claims 4, 5, and 9, instead concluding: "the *'984* patent is declared invalid." *Rosco, 139 F. Supp. 2d at 303.* On remand, the district court should consider these claims.

The district court found that the *'357* patent inherently disclosed the invention of the *'984* patent under *35 U.S.C. § 102*(e), such that one skilled in the art would read the *'357* patent as disclosing a mirror with varying radius of curvature: "the *'357* Patent shows a mirror with a varying radius [**15] of curvature based on the inherent nature of such a characteristic." *Rosco, 139 F. Supp. 2d at 301.* The district court concluded that

"one skilled in the art could produce the results claimed in the *'984* Patent simply by practicing the *'357* Patent, i.e., the result flows naturally from the express disclosures of the *'357* Patent whether or not others are aware of it." *Id. at 300.* In reaching this conclusion, the district court relied on Benjamin Englander's n5 testimony that "Rosco would have preferred to have a mirror that had a constant radius of curvature, . . . [but] the vacuum thermoforming process used to manufacture such mirrors of necessity yields a mirror with a varying radius of curvature." *Id. at 301-02.* Noting that "this evidence was not contradicted at trial," the court concluded that "anyone practicing the *'357* patent by attempting to manufacture it would, on the uncontradicted evidence at trial, come up with a mirror with a varying radius of curvature." *Id. at 301.*

> n5 Rosco is a closely held corporation owned by the Englander family: Solomon Englander, Rosco's president (father); Benjamin Englander, Rosco's vice president of engineering (son); Daniel Englander, Rosco's vice president of finance (son); and Gertrude Englander (mother).

[**16]

We disagree. [HN6] Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).* "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295, 63 U.S.P.Q.2D (BNA) 1597, 1599 (Fed. Cir. 2002)* (quoting *In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2D (BNA) 1949, 1950-51 (Fed. Cir. 1999)).* The vacuum thermoforming process, however, is not specified in the *'357* patent. [*1381] Thus, the question is not whether the manufacture of the mirror using this process inherently results in a varying radius of curvature along the major axis, but whether one skilled in the art would read the *'357* patent as inherently disclosing the invention of the *'984* patent, that is, whether one [**17] skilled in the art would read the *'357* patent as showing a mirror of varying radius of curvature along the major axis. There is no evidence in the record to support a finding that one skilled in the art would so read the *'357* patent. Englander's testimony only purports to establish that mirrors manufactured using the vacuum thermoforming process yield a varying radius of curvature along the major axis, but does not purport to establish that the mirror of the *'357* patent can only be manufactured by that particular process. At oral argument, counsel for Rosco could not identify any evidence that one skilled in the art would read the *'357* patent as inherently disclosing a mirror with varying radius of curvature along the major axis. We accordingly reverse the district court's conclusion that the *'984* patent is invalid under section 102(e).

The district court also found claims 1-3 and 6-8 of the *'984* patent invalid under section 102(g) in view of Rosco's pre-1992 products, finding that Rosco made the invention of the *'984* patent before the *'984* critical date. [HN7] A patent is invalid under section 102(g)(2) if "before the applicant's invention thereof the invention was made in this country [**18] by another who had not abandoned, suppressed, or concealed it." *35 U.S.C. § 102*(g)(2) (2000); *Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334, 1339, 60 U.S.P.Q.2D (BNA) 1519, 1522 (Fed. Cir. 2001).* Prior invention by another invalidates a claimed invention under section 102(g)(2) if the prior inventor either reduced the invention to practice first, or conceived of the invention first and subsequently reduced the invention to practice. However, "it is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention . . . ." *Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 593, 44 U.S.P.Q.2D (BNA) 1610, 1614* (emphasis in original) (citing *Breen v. Henshaw, 472 F.2d 1398, 1401, 176 U.S.P.Q. (BNA) 519, 521 (CCPA 1973);* see also *Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334, 1341, 60 U.S.P.Q.2D (BNA) 1519, 1523 (Fed. Cir. 2001)* ("There is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the [invention]."). The question is whether Rosco actually recognized and [**19] appreciated a mirror with varying radius of curvature along the major axis of the lens. Though the issue is disputed, particularly with regard to trial exhibit 110, we may assume for present purposes that the earlier Rosco product did in fact have a varying radius of curvature along the major axis of the lens. But there is no evidence that this feature of the invention was recognized and appreciated.

At oral argument we requested Rosco's counsel to identify any evidence that, at the time of invention, Rosco recognized that the mirror it designed had a varying radius of curvature along the major axis, even though Rosco intended to design a mirror with constant curvature along the major axis that would not distort the images in the mirror lens. Counsel pointed to the testimony of Englander, who was asked: "When you came up with the idea of this oval mirror, did you have

any part of your idea, did it relate to this concept of varying curvature?" Englander answered: "The varying curvature, in my mind, it was automatic because this is the process of producing these lenses which has to have, by nature, a various curvature." [*1382] Englander's testimony is self-interested and lacks corroboration. [**20] It is well established that [HN8] a party claiming his own prior inventorship must proffer evidence corroborating his testimony. *Sandt Techs. Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350, 60 U.S.P.Q.2D (BNA) 1091, 1094 (Fed. Cir. 2001).* Englander's testimony is insufficient to constitute clear and convincing evidence that Rosco conceived the invention of the *'984* patent before the *'984* critical date. We therefore reverse the district court's conclusion that the *'984* patent is invalid under section 102(g).

The district court did not decide whether the *'984* patent was invalid under sections 102(a), 102(f), or 103, stating that "since the *'984* Patent is invalid under *35 U.S.C. § 102*(e) and (g), there is no need to consider claims of its invalidity under *35 U.S.C. § § 102*(a), (f), or 103." *Rosco, 139 F. Supp. 2d at 303 n.13.* On remand, the district court should analyze the validity of each claim and should consider validity under sections 102(a), 102(f), and 103.

Finally, the district court rejected Rosco's claim that the *'984* patent was unenforceable for inequitable conduct, stating that "Rosco is not entitled [**21] to judgment that the *'984* patent was inequitably procured." Rosco, Inc. v. Mirror Lite Co., No. CV-96-5658 and CV-99-6211, at 2 (E.D.N.Y. Feb. 21, 2001) (final judgment). The district court made no findings or conclusions supporting this result, and did not expressly consider this claim. n6 Again we hold that a remand is required for necessary findings and conclusions as to each claim.

n6 We reject Mirror Lite's argument that the inequitable conduct issue was not properly raised.

If on remand the district court finds any of the *'984* patent claims not invalid and not unenforceable, the issue of whether those claims were infringed would have to be addressed by the district court.

III Rosco's Tortious Interference Claim

Rosco stated a claim under *15 U.S.C. § 1125*(a) for tortious interference with business relationships based on Mirror Lite's alleged inequitable conduct in securing the *'984* patent. **[A11]**. In a footnote, the district court rejected this claim on the ground that [**22] it had been abandoned:

> The Court informed counsel for both parties that the summary judgment opinion . . . did not dispose of Rosco's claim of tortious interference with business relations . . . and invited the parties to submit briefing on this issue. Rosco has not pursued this cause of action at all in either of its two post-trial briefs. Therefore, the Court must consider that Rosco has abandoned this cause of action.

Rosco, 139 F. Supp. 2d at 304 n.14. At oral argument Mirror Lite, with commendable candor, agreed that this claim had not been abandoned, because Rosco had in fact briefed the issue in its post-trial brief. We agree, and remand for findings and conclusions relating to this claim based on the record established at trial.

IV Rosco's Misrepresentation Claim

The district court dismissed on summary judgment Rosco's claim that Mirror Lite engaged in unfair competition under *15 U.S.C. § 1125*(a) by publishing disparaging statements about Rosco's oval mirror, Rosco, Inc. v. Mirror Lite Co., No. CV-96-5658, at 30 (E.D.N.Y. June 2, 1999) (order granting summary judgment in part) and denied reconsideration. Rosco alleged [**23] that Mirror Lite misrepresented Rosco's oval mirror to consumers by publishing [*1383] various statements, such as that Rosco's mirror did not comply with federal safety standards and that school bus owners must replace their mirrors with mirrors of "identical appearance" to comply with federal safety standards. [HN9] To establish misrepresentation under *15 U.S.C. § 1125*(a), a plaintiff must show that the statement at issue is either (1) literally false as a factual matter; or (2) although literally true, it is likely to deceive or confuse customers. *Nat'l Basketball Assoc. v. Motorola, Inc., 105 F.3d 841, 855, 41 U.S.P.Q.2D (BNA) 1585, 1597 (2d Cir. 1997).* The plaintiff must also prove that the "defendant misrepresented an 'inherent quality or characteristic' of the product." *Nat'l Assoc. of Pharm. Mfrs. v. Ayerst Labs., 850 F.2d 904, 917, 7 U.S.P.Q.2D (BNA) 1530, 1540 (2d Cir. 1988)* (citation omitted).

The district court dismissed Rosco's unfair competition claim after finding these statements "literally true," and that they were not "implicitly false" so as to cause confusion. Rosco, Inc. v. Mirror Lite Co., No. CV-96-5658, at 27-28 (E.D.N.Y. June 2, 1999) [**24] (order granting summary judgment in part). We affirm the district court. Rosco did not offer evidence of clear untruth or implied untruth sufficient to defeat summary judgment. We uphold the district court's grant of

summary judgment as to this claim, because there is no genuine issue as to the truth of those statements.

V Rosco's Common Law Trademark Infringement Claim

The district court rejected Rosco's claim that Mirror Lite infringed its "Hawk Eye" and "Mini Hawk Eye" common law marks in violation of *15 U.S.C. § 1125*(a): "Rosco has produced no evidence in the form of consumer surveys, advertising expenditure, or unsolicited media coverage that 'Hawk Eye' and 'Mini Hawk Eye' have attained secondary meaning. Nor has Rosco established a likelihood of confusion, given the sophistication of the purchasers in the school bus mirror market." n7 *Rosco, 139 F. Supp. 2d at 303-04.*

n7 While Rosco's "Hawk Eye" mark was apparently a registered trademark, Rosco asserted claims under [HN10] *15 U.S.C. § 1125*(a), which protects unregistered marks. We therefore do not understand Rosco to have asserted a claim of trademark infringement.

[**25]

Rosco asserted its claim under *15 U.S.C. § 1125*(a), section 43(a) of the Lanham Act. [HN11] Unregistered marks receive essentially the same protection as registered marks: "The Court interprets this section [§ 43(a)] as having created a federal cause of action for infringement of unregistered trademark or trade dress and concludes that such a mark or trade dress should receive essentially the same protection as those that are registered." *Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 776, 120 L. Ed. 2d 615, 112 S. Ct. 2753 (1992)* (Stevens, J., concurring). McCarthy notes: "When section 43(a) is used as a federal vehicle for assertion of traditional claims of infringement of trademarks, . . . the courts have used as substantive law the traditional rules of trademarks and unfair competition law," and concludes that "the test of liability is likelihood of confusion." 4 McCarthy on Trademarks and Unfair Competition § 27:18 at 27-32 (4th ed. 2002). See also *New West Corp. v. NYM Co. of Cal., 595 F.2d 1194, 1201, 202 U.S.P.Q. (BNA) 643, 649 (9th Cir. 1979)* ("Under [§ 43(a)] the ultimate test is whether the public is likely to be [**26] deceived or confused by the similarity of the marks. . . . Whether we call the violation infringement, unfair competition or false designation of origin, the test is identical--is there a 'likelihood of confusion'?").

[*1384] To prevail on a claim for common law trademark infringement under section 1125(a), a party must show likelihood of confusion. This is required by the statute itself: section 1125(a) is triggered by a use that "is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association" of the user with the senior user. *15 U.S.C. § 1125*(a) (2000). Rosco does not challenge the district court's finding that it failed to show likelihood of confusion.

Because Rosco did not show likelihood of confusion, we affirm the district court's denial of this claim. We need not address the district court's alternative ground for rejecting this claim, i.e., that Rosco failed to establish secondary meaning. n8

n8 Three other claims under *15 U.S.C. § 1125* were originally asserted in the district court: Rosco alleged that Mirror Lite infringed its alleged common law trademark rights in its product numbering system; infringed the trade dress of its "Hawk Eye" mirrors; and infringed its alleged common law trademark rights in the "Eagle Eye" mark. It is not clear whether Rosco's common law trademark claim as to its product numbering system is at issue on appeal, but we find no error with the district court's rejection of that claim. As for the trade dress claim, the district court concluded that Rosco abandoned its trade dress claim in light of the Supreme Court's decision in *Wal-Mart Stores, Inc. v. Samara Brothers, Inc., 529 U.S. 205, 216, 146 L. Ed. 2d 182, 120 S. Ct. 1339 (2000).* Rosco does not argue to the contrary. Finally, the district court found that Rosco abandoned its claim that its alleged common law trademark rights in the "Eagle Eye" mark were infringed. We do not understand this ruling to be challenged on appeal.

[**27]

Finally, we have considered Mirror Lite's procedural objections and find them to be without merit.

CONCLUSION

On remand, the following issues should be addressed on the basis of the existing trial record:

1) whether Mirror Lite has shown by clear and convincing evidence that Rosco's *'357* design patent is invalid under *35 U.S.C. § 103;*

2) whether Rosco has shown by preponderant evidence that Mirror Lite

infringed (if valid) Rosco's *'357* design patent;

3) whether Rosco has shown by clear and convincing evidence that Mirror Lite's *'984* patent is invalid under *35 U.S.C. § § 102*(a), 102(f), and 103, considering each claim separately;

4) whether Rosco has shown by clear and convincing evidence that Mirror Lite's *'984* patent is unenforceable due to inequitable conduct;

5) whether Mirror Lite has shown by preponderant evidence that Rosco infringed any valid claim of its *'984* patent (if those claims are valid and enforceable); and

6) whether Rosco has shown that Mirror Lite engaged in tortious interference with business relations through inequitable conduct in procuring the *'984* patent.

COSTS

No costs.

[**28] AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED.

Exhibit G

In re Robertson, 169 F.3d 743 (Fed. Cir. 1999)

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

LEXSEE 49 USPQ 2D 1949

IN RE ANTHONY J. ROBERTSON and CHARLES L. SCRIPPS

98-1270

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

169 F.3d 743; 1999 U.S. App. LEXIS 3224; 49 U.S.P.Q.2D (BNA) 1949

February 25, 1999, Decided

PRIOR HISTORY: [**1] Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/171,484).

DISPOSITION: REVERSED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant challenged the judgment of the Patent and Trademark Office Board of Patent Appeals and Interferences, which found that a claim in appellant's patent application was anticipated by and obvious over appellee's patent.

OVERVIEW: Because the evidence relied upon by the Board of Patent Appeals and Interferences (board) was insufficient to establish inherency, the court reversed the board's judgment. The devices in question involved diaper fasteners. On appeal, the court stated that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter was necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Because the board failed to cite extrinsic evidence indicating that the devices in question performed the same function, its finding of inherency was insufficient because it rested upon probabilities or possibilities.

OUTCOME: The court reversed the judgment of the Board of Patent Appeals and Interferences because the evidence upon which its decision was based was insufficient to establish inherency in that it rested on probabilities and possibilities.

LexisNexis(R) Headnotes

Patent Law > Anticipation & Novelty > General Overview

[HN1] Anticipation under *35 U.S.C.S. § 102*(e) requires that each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Patent Law > Anticipation & Novelty > General Overview

[HN2] If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

COUNSEL: Kenneth R. Adamo, Jones, Day, Reavis & Pogue, of Cleveland, Ohio, argued for appellant. With him on the brief were Calvin P. Griffith, and Gregory A. Castanias, of Washington, DC. Of counsel on the brief was Steven W. Miller, The Proctor & Gamble Company, of Cincinnati, Ohio.

Linda Moncys Isacson, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With her on the brief were Albin F. Drost, Acting Solicitor, and John M. Whealan, Associate Solicitor.

JUDGES: Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge. Opinion for the court filed by Senior Circuit

Judge FRIEDMAN, in which Circuit Judge NEWMAN joins. Concurring opinion filed by Circuit Judge RADER.

OPINIONBY: FRIEDMAN

OPINION: [*744] FRIEDMAN, Senior Circuit Judge:

This appeal challenges the decision of the Board of Patent Appeals and Interferences (Board) that claim 76 in the appellants' patent application was anticipated by and obvious over United States Patent No. *4,895,569* (the Wilson patent). We reverse.

I

Both claim 76 and [**2] Wilson involve fastening and disposal systems for diapers. In both, the body of the diaper features a small front and a larger rear section. The outer edges of those sections are attached at the wearer's waist in the hip area. Once the diaper is soiled and then removed, the smaller front section is rolled up into the larger rear section and secured in this rolled-up configuration by fasteners.

The appellants' application is for "an improved mechanical fastening system for . . . disposable absorbent articles [i.e., diapers] that provides convenient disposal of the absorbent article." Claim 76 covers:

> [A] mechanical fastening system for forming side closures . . . comprising
>
> a closure member . . . comprising a first mechanical fastening means for forming a closure, said first mechanical fastening means comprising a first fastening element;
>
> a landing member . . . comprising a second mechanical fastening means for forming a closure with said first mechanical fastening means, said second mechanical fastening means comprising a second fastening element mechanically engageable with said first element; and
>
> disposal means for allowing the absorbent article [**3] to be secured in a disposal configuration after use, said disposal means comprising a third mechanical fastening means for securing the absorbent article in the disposal configuration, said third mechanical fastening means comprising a third fastening element mechanically engageable with said first fastening element . . .

Claim 76 thus provides for two mechanical fastening means to attach the diaper to the wearer and a third such means for securing the diaper for disposal.

The Wilson patent discloses two snap elements on fastening strips attached to the outer edges of the front and rear hip sections of the garment. The fastening strips may also include "secondary load-bearing closure means" - additional fasteners to secure the garment; they may be identical to the snaps.

Wilson also states:

> Disposal of the soiled garment upon removal from the body is easily accomplished by folding the front panel . . . inwardly and then fastening the rear pair of mating fastener members . . . to one another, thus neatly bundling the garment into a closed compact package for disposal.

[*745] In other words, Wilson does not provide a separate fastening means to be used in disposing of the [**4] diaper. Instead, it suggests that disposal of the used diaper may be "easily accomplished" by rolling it up and employing the same fasteners used to attach the diaper to the wearer to form "a closed compact package for disposal."

In holding that the invention claim 76 covers was anticipated by Wilson, the Board did not hold that Wilson set forth a third fastening means. Instead, it found that Wilson anticipated claim 76 "under principles of inherency." Applying the language of claim 76 to the operation of Wilson, it concluded that "an artisan would readily understand the disposable absorbent garment of Wilson . . . as being inherently capable of [making the secondary load-bearing closure means] (third fastening element) mechanically engageable with [the other snap fasteners on the fastening strip] (first fastening element)" - i.e., using the secondary closure not with its mate, but with one of the primary snap fasteners. The Board summarily affirmed the examiner's alternative ruling that claim 76 would have been obvious in light of Wilson because "claim 76 lacks novelty."

II

[HN1] Anticipation under *35 U.S.C. § 102*(e) requires that "each and every element as set forth in the [**5] claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987).*

A. The Wilson patent does not expressly include a third fastening means for disposal of the diaper, as claim 76 requires. That means is separate from and in addition to the other mechanical fastening means and performs a different function than they do. Indeed, Wilson merely suggests that the diaper may be closed for disposal by using the same fastening means that are used for initially attaching the diaper to the body.

B. [HN2] If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).* "Inherency, however, may not be established by probabilities or [**6] possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id. at 1269, 20 U.S.P.Q.2D (BNA) at 1749* (quoting *In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).*

In finding anticipation by inherency, the Board ignored the foregoing critical principles. The Board made no attempt to show that the fastening mechanisms of Wilson that were used to attach the diaper to the wearer also "necessarily" disclosed the third separate fastening mechanism of claim 76 used to close the diaper for disposal, or that an artisan of ordinary skill would so recognize. It cited no extrinsic evidence so indicating.

Instead, the Board ruled that one of the fastening means for attaching the diaper to the wearer also could operate as a third fastening means to close the diaper for disposal and that Wilson therefore inherently contained all the elements of claim 76. In doing so, the Board failed to recognize that the third mechanical fastening means in claim 76, used to secure the diaper for disposal, was separate from and independent of the two other mechanical means used to attach the diaper to the person. The Board's theory that [**7] these two fastening devices in Wilson were capable of being intermingled to perform the same function as the third and first fastening elements in claim 76 is insufficient to show that the latter device was inherent in Wilson. Indeed, the Board's analysis rests upon the very kind of probability or possibility - the odd use of fasteners with other than their mates - that this court has pointed out is insufficient to establish inherency.

III

The Board's entire discussion of obviousness was as follows:

> [*746] **The rejection of claim 76 under *35 USC § 103***
>
> We sustain the rejection of claim 76 under *35 USC § 103.*
>
> Above, we found that claim 76 lacks novelty. Lack of novelty is the ultimate of obviousness. See *In re Fracalossi, 681 F.2d 792, 794, 215 U.S.P.Q. (BNA) 569, 571 (CCPA 1982).* Thus, claim 76 is appropriately rejected under *35 USC § 103* as being unpatentable.

The "lack of novelty" upon which the Board based its conclusion of obviousness, however, was its finding of anticipation. Our rejection of that finding eliminates the sole basis of the Board's obviousness determination, which therefore cannot stand. See *In re Adams, 53 C.C.P.A. 1433, 364 F.2d 473, 480, 150 U.S.P.Q. 646,* [**8] *651 (C.C.P.A. 1966).*

In his brief the Commissioner argues:

> Moreover, even if this court interprets claim 76 to require two separate fasteners to perform the closure and disposal functions, it would have been well within the knowledge of one of ordinary skill in the art to take Wilson's one fastener and make it into two separate fasteners. See *[In re] Graves, 69 F.3d [1147,] 1152, 36 U.S.P.Q.2D (BNA) [1697,] 1701* [(Fed. Cir. 1995)] (When evaluating a reference, it is appropriate to consider the knowledge of a skilled artisan in combination with the teaching of the reference.). Accordingly, claim 76 would have been obvious to one of ordinary skill in the art, and the rejection should be affirmed by this Court.

That, of course, was not the ground on which the Board based its obviousness ruling. We decline to consider counsel's newly-minted theory as an alternative ground for upholding the agency's decision. See *In re Soni, 54 F.3d 746, 751, 34 U.S.P.Q.2D (BNA) 1684, 1688 (Fed. Cir. 1995)* (citing *In re DeBlauwe, 736 F.2d 699, 705 n.7, 222 U.S.P.Q. 191, 196 n.7 (Fed. Cir. 1984).* The Board's obviousness ruling cannot be sustained on the ground the Board gave. [**9]

CONCLUSION

The decision of the Board of Patent Appeals and Interferences affirming the examiner's rejection of claim

76 as anticipated by and obvious over the Wilson patent is

REVERSED.

CONCURBY: RADER

CONCUR: RADER, Circuit Judge, concurring.

Robertson asserts that the prior art Wilson patent does not teach three elements of claim 76: a "third mechanical fastening means," a disposal means on the "outside surface" of the body portion, and end regions that are "in an overlapping configuration when worn." In reversing the Board, this court relies solely on the purported failure of Wilson to teach the third fastening means. Because I believe Wilson teaches such a means, but does not teach the other two limitations at issue, I concur.

In its analysis, this court assumes without discussion that the claimed "third mechanical fastening means" covers a separate third mechanical fastening means. This issue is key, for if the claim does not require a separate third fastening means, but instead allows the first fastening means to also serve as the third, then the prior art Wilson patent clearly teaches that element of the claim. For two reasons, this claim does not, to my eyes, [**10] require a separate third fastening means. First, the claim does not specifically recite a separate third fastening means. Second, because the claim is in means-plus-function form, this court consults the specification to identify structure. The specification explicitly teaches that the first and third fastening elements can be the same so long as they are complementary, as they are in Wilson. Accordingly, I agree with the Board that Wilson teaches the claimed "third fastening element."

Wilson does not, however, teach either of the other two claim limitations at issue. As to the disposal means on the "outside surface" of the body portion, Wilson's figs. 12 and 13a-d show the disposal means on the inside of the body portion. As to the end regions that are "in an overlapping configuration when worn," Wilson explicitly teaches that the end regions should abut, not overlap, when worn. To overcome these teachings, the Board relied on the following statement in Wilson: "Further, the fastener members [*747] need not be previously mounted on a separate strip as shown then bonded . . . to the stretchable outer cover . . . . Multi-component snaps are available which may be applied directly to a [**11] stretchable outer cover material . . . ." Col. 7, l. 65 to col. 8, l. 3. The Board opined that applying snaps directly to the outer cover would result in both a disposal means on the "outside surface" and end regions "in an overlapping configuration when worn." Simply put, the Board has put more weight on this teaching than it can bear. It is far from clear what effect applying the snaps directly to the outer cover will have on the Wilson diaper configuration, let alone that it will result in a configuration satisfying the claim elements at issue. Accordingly, because I believe that the Board clearly erred in this interpretation of Wilson, I would reverse on this ground.

Exhibit H

Continental Can Co. v Monsanto 948 F.2d 1264 (Fed. Cir. 1991)

Introduced in an amendment and response dated July 1, 2003

Acknowledged in the Office Action dated January 28, 2004

LEXSEE 20 USPQ 2D 1746

CONTINENTAL CAN COMPANY USA, INC. and CONTINENTAL PET TECHNOLOGIES, INC., Plaintiffs-Appellants, v. MONSANTO COMPANY, HOOVER UNIVERSAL, INC. and JOHNSON CONTROLS, INC., Defendants-Appellees

No. 90-1328

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

948 F.2d 1264; 1991 U.S. App. LEXIS 26994; 20 U.S.P.Q.2D (BNA) 1746

November 13, 1991, Decided

SUBSEQUENT HISTORY:

Rehearing Denied December 26, 1991, Reported at: *1991 U.S. App. LEXIS 29979.*

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Southern District of Ohio; Judge Spiegel.

DISPOSITION:

Reversed in Part, Vacated in Part, and Remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff appealed an order of United States District Court for the Southern District of Ohio that granted partial summary judgment in favor of defendant, in an action alleging patent infringement for the use of a plastic bottle bottom.

OVERVIEW: Plaintiff filed suit alleging patent infringement for defendant's use of a plastic bottle bottom structure. Plaintiff appealed the trial court's order of partial summary judgment for defendant. The court reversed and remanded. The court held summary judgment was not proper in light of *35 U.S.C.S. § 103,* which required analysis of not whether the differences in the structure were simple enhancements, but whether it would have been obvious to make the claimed structure. The court found that there existed material issues of disputed facts, which precluded summary judgment, on the production of hollow ribs using a blow molding process. The court also held that the trial court erred in determining that the patented bottle was on sale more than one year prior to application for patent, thereby barring patent entitlement. The court held that a product is not considered on sale until the availability of the product to the public.

OUTCOME: The court reversed an order granting defendant partial summary judgment and remanded because the trial court failed to determine whether it would have been obvious to make the claimed structure and erred in determining that the patented bottle was on sale even though it was not available to the public.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN1] An issue may be decided on motion for summary judgment when there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law.

Civil Procedure > Summary Judgment > Summary Judgment Standard

[HN2] The movant's burden in a summary judgment motion is to show that no fact material to the issue is in dispute, that even if all material factual inferences are drawn in favor of the non-movant the movant is entitled to judgment as a matter of law.

Patent Law > Infringement Actions > Summary Judgment > General Overview

[HN3] Summary judgment is as available in patent cases as in other areas of litigation.

Patent Law > Anticipation & Novelty > General Overview
[HN4] See *35 U.S.C.S. § 102*(a).

Patent Law > Anticipation & Novelty > General Overview
[HN5] Anticipation under *35 U.S.C.S. § 102*(a) requires that the identical invention that is claimed was previously known to others and thus is not new.

Patent Law > Nonobviousness > Evidence & Procedure > Presumptions & Proof
Patent Law > Inequitable Conduct > General Overview
Patent Law > Anticipation & Novelty > General Overview
[HN6] When more than one reference is required to establish unpatentability of the claimed invention anticipation under *35 U.S.C.S. § 102* can not be found, and validity is determined in terms of *35 U.S.C.S. § 103.*

Patent Law > Anticipation & Novelty > General Overview
[HN7] To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN8] Modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges. It is not, however, a substitute for determination of patentability in terms of *35 U.S.C.S. § 103.*

Patent Law > Statutory Bars > On Sale Bar > General Overview
Patent Law > Statutory Bars > Public Use Bar > General Overview
[HN9] See *35 U.S.C.S. § 102*(b).

Patent Law > Statutory Bars > On Sale Bar > General Overview

[HN10] The on sale bar of *35 U.S.C.S. § 102*(b) does not arise simply because the intended customer was participating in development and testing.

Patent Law > Statutory Bars > On Sale Bar > General Overview
[HN11] Various factors pertinent to the on sale bar when there is an issue concerning the relationship between the patentee and the customer are: whether there was a need for testing by other than the patentee; the amount of control exercised; the stage of development of the invention; whether payments were made and the basis thereof; and whether confidentiality was required; and whether technological changes were made. All of the circumstances attending the relationship must be considered in light of the public policy underlying *35 U.S.C.S § 102*(b).

Patent Law > Statutory Bars > On Sale Bar > General Overview
[HN12] The on sale bar is measured by the time the public came into possession of the invention. What starts the period running is the availability of the invention to the public through the categories of disclosure enumerated in *35 U.S.C.S. § 102*(b).

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN13] Obviousness, *35 U.S.C.S. § 103,* is reviewed as a legal conclusion based upon underlying facts of four general categories: the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill at the time the invention was made, and any objective considerations that may be present.

Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN14] When differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the court must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made.

Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations
[HN15] It is not necessary that the patented invention be solely responsible for the commercial success in order for this factor to be given weight appropriate to the

evidence, along with other pertinent factors, in determining obviousness.

COUNSEL:

Eugene F. Friedman, Eugene F. Friedman, Ltd., of Chicago, Illinois, argued for Plaintiffs-Appellants. With him on the brief were Edwin C. Thomas, III and David M. Novak, Bell, Boyd & Lloyd, of Chicago, Illinois. Also on the brief was Kurt L. Grossman, Wood, Herron & Evans, of Cincinnati, Ohio.

Henry J. Renk, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for Defendants-Appellees. With him on the brief were Lawrence F. Scinto and Bruce C. Haas. Also on the brief were Jacob K. Stein, Deborah DeLong, Thompson, Hine & Flory, of Cincinnati, Ohio, Lawrence L. Limpus, Monsanto Company, of St. Louis, Missouri and Edward L. Levine, Johnson Controls, Inc., of Milwaukee, Wisconsin.

JUDGES:

Newman, Archer, and Rader, Circuit Judges.

OPINIONBY:

NEWMAN

OPINION:

[*1265] NEWMAN, Circuit Judge

Continental Can Company USA and Continental PET Technologies (collectively "Continental") appeal the partial summary judgment of the United States District Court for the Southern District of Ohio, holding that United States Patent No. *4,108,324* (the Conobase or *'324* [**2] patent) is invalid. n1 Final judgment was entered on this issue, for the purpose of appeal.

n1 *Continental Can Co. USA v. Monsanto Co., 1989 U.S. Dist. LEXIS 13417, 11 U.S.P.Q.2d (BNA) 1761 (S.D. Ohio 1989), reconsid. denied*, No. C-1-86-1213 (S.D. Ohio Nov. 9, 1989).

Summary Judgment

[HN1] An issue may be decided on motion for summary judgment when there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 325-26, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1571, 18 U.S.P.Q.2d (BNA) 1001, 1005 (Fed. Cir. 1991).* [HN2] The movant's burden is to show that no fact material to the issue is in dispute, that even if all material factual inferences are drawn in favor of the non-movant the movant is entitled to judgment as a matter of law. *Id.* [HN3] Summary judgment is as available in patent cases [**3] as in other areas of litigation. *Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 778-79, 218 U.S.P.Q. (BNA) 673, 675 (Fed. Cir. 1983)*

The purpose of the summary process is to avoid a clearly unnecessary trial, *Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986);* it is not designed to substitute lawyers' advocacy for evidence, or affidavits for examination before the fact-finder, when there is a genuine issue for trial. As stated in *Adickes v. S.H. Kress & Co., 398 U.S. 144, 176, 26 L. Ed. 2d 142, 90 S. Ct. 1598 (1970)* (Black, J., concurring), "the right to confront, cross-examine and impeach adverse witnesses is one of the most fundamental rights sought to be preserved by the Seventh Amendment". *See also Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 473, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1962).*

While facilitating the disposition of legally meritless suits, when summary judgment [*1266] is improvidently granted the effect is to prolong litigation and increase its burdens. This is of particular concern in patent disputes, where the patent property is a wasting asset, and justice is ill served by delay in final resolution. [**4] In the case at bar, although some issues could be resolved on the law and undisputed facts, other issues require trial.

The Patented Invention

The *'324* patent, entitled "Ribbed Bottom Structure for Plastic Container", inventors Suppayan M. Krishnakumar, Siegfried S. Roy, John F. E. Pocock, Salil K. Das, and Gautam K. Mahajan, is directed to a plastic bottle whose bottom structure has sufficient flexibility to impart improved impact resistance, combined with sufficient rigidity to resist deformation under internal pressure. The patented bottle is said to provide a superior combination of these properties. The bottom structure is illustrated as follows:

[SEE FIG 2 IN ORIGINAL]

Claim 1 is the broadest claim of the *'324* patent:

> 1. A container having a sidewall and a bottom structure closing the container at an end portion of the sidewall,

> the outer surface of the bottom structure comprising a central concavity,
>
> a convex heel surrounding the concavity and merging therewith and with the sidewall end portion, the lowermost points of the heel lying in a common plane,
>
> and a plurality of ribs interrupting the outer surface of the concavity and distributed in a symmetrical [**5] array,
>
> each rib extending longitudinally in the direction of the heel and downwardly from an inner portion of the concavity, whereby the outer end portion of each rib is lower than the inner end portion thereof,
>
> characterized by the feature that the ribs are hollow.

Claims 2 through 5 include additional limitations, described as contributing to the structure's rigidity, flexibility, or both. Claim 2 specifies the ratios of thickness of the walls of the bottom structure to the thickness of the sidewall end portions. Claim 3 specifies that the margins of each rib merge smoothly with adjacent portions of the bottom structure. Claim 4 specifies that each rib is convex relative to the bottom structure. Claim 5 specifies that each rib is of fusiform (a gently tapered shape at the ends) configuration. Each claim carries an independent presumption of validity, [*1267] *35 U.S.C. § 282,* and stands or falls independent of the other claims. *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp., 294 U.S. 477, 487, 79 L. Ed. 1005, 55 S. Ct. 455 (1935).*

Continental brought suit for patent infringement against Monsanto Company and Monsanto's successor in this business, Hoover Universal, Inc. and Hoover's parent [**6] company, Johnson Controls (collectively "Monsanto"). Monsanto moved for partial summary judgment based on issues of validity under *35 U.S.C. § § 102* and 103.

I

35 U.S.C. § 102(a)

The statutory requirement that a patented invention be "new" is tested in accordance with *35 U.S.C. § 102*(a), which provides that:

> § 102. [HN4] A person shall be entitled to a patent unless--
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. . . .

The district court found that all the claims of the *'324* patent were anticipated by U.S. Patent No. *3,468,443* (the Marcus patent). We conclude that the district court erred in claim interpretation, and also found disputed facts adversely to the nonmovant, thus inappropriately deciding the issue summarily.

[HN5] Anticipation under § 102(a) requires that the identical invention that is claimed was previously known to others and thus is not new. *Scripps Clinic, 927 F.2d at 1576, 18 U.S.P.Q.2d at 1010; Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780, 227 U.S.P.Q. (BNA) 773, 777-78 (Fed. Cir. 1985);* [**7] *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984).* [HN6] When more than one reference is required to establish unpatentability of the claimed invention anticipation under § 102 can not be found, and validity is determined in terms of § 103.

It was Monsanto's burden to show that every element of the several claims of the *'324* patent was identically described in the asserted anticipating reference, the Marcus patent. The district court focused on the term "characterized by the feature that the ribs are hollow", which limits all of the *'324* patent claims. Continental argues that the district court incorrectly construed this term, as a matter of law, and that the Marcus patent shows ribs that are not hollow, as that term is used in the *'324* patent. Continental also points to other differences between the *'324* claims and the description in the Marcus patent.

The Marcus patent rib structure is illustrated in Figure 5 and in cross-section in Figure 6:

[SEE FIG.5 IN ORIGINAL]

[SEE FIG.6 IN ORIGINAL]

[*1268] The Marcus patent does not state that its ribs are "hollow", or use a similar term. Continental's witnesses [**8] testified by deposition that the Marcus patent shows solid, not hollow, ribs. A witness (Adomaitis) had stated in an internal memorandum written at Continental in 1969, well before this litigation arose, that "the ribs of their [Marcus'] web can be made of solid beams only." Another witness, *'324* co-inventor Pocock, testified that:

> It seems evident to me that he [Marcus] was trying to produce some kind of container integrity by the production of essentially solid ribs on the bottom of the bottle. It seems to go to great length here to illustrate them as such.

Krishnakumar, another co-inventor, testified that it "is very obvious the ribs are shown solid", and that Figures 5 and 6 as well as Figures 7 through 12 of the Marcus patent all show solid ribs. However, Marcus, testifying for Monsanto, testified that his ribs were hollow, and that conventional blow molding would inherently produce hollow ribs.

The district court defined "hollow" as meaning that "the inside contour of the ribs generally follows the outside contour thereof", a definition on which the parties agreed. *Continental, 11 U.S.P.Q.2d at 1764.* See the court's opinion, *11 U.S.P.Q.2d at 1764-68,* [**9] for various sketches made by the witnesses. Continental states that the district court erred in construing "hollow", and that the phrase "characterized by the feature that the ribs are hollow" must be construed in terms of the patent in which it appears. *See, e.g., Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1021, 4 U.S.P.Q.2d (BNA) 1283, 1286 (Fed. Cir. 1987).* The *'324* patent explicitly distinguished the Marcus patent teachings, stating that the *'324* ribs are, unlike Marcus, not filled with plastic. The *'324* specification uses the term "hollow", as do the prosecution history and the claims, for this purpose. The *'324* patent's usage of "hollow" is illustrated in the rib cross-section in Figure 5A:

[SEE FIG 5A IN ORIGINAL]

The Marcus patent's rib structure thus was explicitly differentiated by the term "hollow" as used in the *'324* specification, drawings, and prosecution history. Since the claim term must be construed as used by the patentee, the district court erred in its construction of the *'324* claim term "hollow". On correct claim construction, the factual question of anticipation must be decided.

Monsanto's argument is that hollow [**10] ribs were inherently produced by Marcus. Monsanto thus argues that anticipation lies because the Marcus patent's ribs are "inherently" hollow, regardless of how they are shown in the Marcus patent. Monsanto argues that because the Marcus ribs are formed by injection blow molding, which is the same process described for the Conobase *'324* ribs, hollow ribs are inherently disclosed in the Marcus patent.

[HN7] To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (CCPA 1981)* (quoting *Hansgirg v. Kemmer, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 U.S.P.Q. (BNA) 665, 667 (CCPA 1939))* provides:

> [*1269] Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [Citations omitted.] If, [**11] however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

This [HN8] modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges. It is not, however, a substitute for determination of patentability in terms of § 103.

Continental does not dispute the applicability of the injection blow molding process. However, Continental disputes the material fact of whether this process necessarily produced "hollow" ribs in the Marcus base structure, as the term "hollow" is used in the *'324* patent. Resolution of this disputed fact adversely to Continental was improper on summary judgment. The grant of summary judgment of anticipation under § 102(a) is vacated. The issue requires trial.

II

35 U.S.C. § 102(b)

The district court also held that [**12] the Marcus bottle was on sale, *35 U.S.C. § 102*(b). Section 102(b) bars entitlement to a patent when:

> [HN9] (b) the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . . .

The Marcus bottle was developed some ten years before the filing date of the *'324* patent, during a project wherein Marcus' employer, Admiral Plastics or APL Corporation, entered into agreements with the Coca-Cola Company for the development of a suitable plastic bottle. The agreements provided that Admiral Plastics would make and Coca-Cola would test the bottles, and that if a satisfactory bottle was developed it would be manufactured by Admiral and purchased by Coca-Cola. Minimum commercial quantities and maximum commercial prices were stated in an agreement, and costs were a matter of discussion. Admiral produced a variety of bottle shapes, including the Marcus bottle. The project was terminated after about two years, because the "mechanical performance" requirements were not met, as Coca-Cola wrote at the time.

The district court reasoned that this project "called for the eventual marketing of the Marcus bottles once [**13] all technical difficulties were resolved", *Continental, 11 U.S.P.Q.2d at 1766,* and on this basis held that the Marcus bottles were on sale. This holding was in error, for [HN10] the "on sale" bar of § 102(b) does not arise simply because the intended customer was participating in development and testing. *See Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 164-65, 228 U.S.P.Q. (BNA) 356, 358 (Fed. Cir. 1986).* In *Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1563-65, 4 U.S.P.Q.2d (BNA) 1210, 1213-15 (Fed. Cir. 1987),* this court summarized [HN11] various factors pertinent to the "on sale" bar when there is an issue concerning the relationship between the patentee and the customer: for example, whether there was a need for testing by other than the patentee; the amount of control exercised; the stage of development of the invention; whether payments were made and the basis thereof; whether confidentiality was required; and whether technological changes were made. All of the circumstances attending the relationship must be considered in light of the public policy underlying § 102(b). *UMC Electronics Co. v. United States, 816 F.2d 647, 656, 2 U.S.P.Q.2d (BNA) 1465, 1471-72 (Fed. Cir. 1987),* [**14] *cert. denied, 484 U.S. 1025, 98 L. Ed. 2d 761, 108 S. Ct. 748 (1988).*

The district court acknowledged that all technical difficulties were not resolved and that no sales were ever made. [*1270] Although Admiral Plastics' hope was surely commercial sales, and the record shows that prices and quantities were discussed, this does not of itself place the subject matter "on sale" in the sense of § 102(b). The Marcus bottle was part of a terminated development project that never bore commercial fruit and was cloaked in confidentiality. While the line is not always bright between development and being on sale, see generally *UMC Electronics, supra,* in this case the line was not crossed. [HN12] The "on sale" bar is measured by "the time the public came into possession of the invention", *id. at 655, 2 U.S.P.Q. 2d at 1471* (quoting *In re Foster, 52 C.C.P.A. 1808, 343 F.2d 980, 987-88, 145 U.S.P.Q. (BNA) 166, 173 (CCPA 1965), cert. denied, 383 U.S. 966, 16 L. Ed. 2d 307, 86 S. Ct. 1270, 149 U.S.P.Q. (BNA) 906 (1966)* ("What starts the period running is clearly the availability of the invention *to the public* through the categories of disclosure enumerated in 102(b). . . ." (emphasis in original))). [**15] We conclude that the district court erred in holding that the circumstances that here existed placed the Marcus bottles "on sale" in terms of § 102(b). We therefore reverse and direct that on remand judgment on this issue shall be entered in favor of Continental, as a matter of law.

III

35 U.S.C. § 103

[HN13] Obviousness, *35 U.S.C. § 103,* is reviewed as a legal conclusion based upon underlying facts of four general categories, *viz.* the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill at the time the invention was made, and any objective considerations that may be present. *Graham v. John Deere Co., 383 U.S. 1, 17, 15 L. Ed. 2d 545, 86 S. Ct. 684, 148 U.S.P.Q. (BNA) 459 (1966); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1137-38, 227 U.S.P.Q. (BNA) 543, 547 (F.C. Cir. 1985).*

The parties agreed that the scope and content of the prior art was adequately represented by four references: the Marcus patent discussed in Part I *ante,* a patent to Colombo (U.S. Patent No. *3,403,804*), and two patents owned by Continental, U.S. Patent No. *3,598,270* (the Petaloid patent), and No. 3,935,955 (the Decaloid patent). They agreed [**16] on little else. In granting summary judgment of invalidity for obviousness, the district court found certain disputed material facts and misapplied certain precepts of law. We conclude that the issue was not amenable to summary resolution. Although it is not entirely clear how the references were combined by the court, we shall review the references briefly, in order to explain our conclusion.

The Petaloid Patent

The district court referred to the deposition testimony of Siegfried Roy, one of the co-inventors of the *'324* patent, that the Petaloid base, inverted, was similar to the Conobase. Continental points out that neither Roy nor any other deponent suggested that the Petaloid base could be or should be inverted, or that inversion would provide an improved base structure. In *In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984)* this court held that although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.

Continental points out that the Petaloid description differs in several other ways from [**17] the *'324* invention. In the *'324* structure the outer end of each rib is lower than the inner end, whereas in the Petaloid structure the outer ends of the ribs are higher than the inner ends; that is, the ribs in the Petaloid base extend upward from the center to the sidewall. The Petaloid bottle is supported on feet extending between the ribs, such feet being the locations for stress concentrations. The following drawing is from the Petaloid patent:

[*1271] [SEE FIG 3 IN ORIGINAL]

Continental states that the *'324* Conobase is not only different, but avoids the stress concentrations of the Petaloid device, thus enhancing impact resistance. Monsanto argues that Continental simply used the Petaloid hollow ribs in combination with the Marcus patent. This requires determination of whether there was something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination, in a way that would produce the *'324* structure. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 U.S.P.Q.2d (BNA) 1434, 1438* (Fed. Cir.), *cert. denied, 488 U.S. 825, 102 L. Ed. 2d 51, 109 S. Ct. 75 (1988).* Continental argues that it is not apparent, [**18] even with hindsight, how any combination of the Petaloid and Marcus patents or other references lead to the *'324* base. The Petaloid patent shows concave ribs that extend all the way to the sidewall, while the Marcus ribs extend "from the heel" toward an annular central ring. The Petaloid base has wide, petal-like, open ribs, while Marcus shows narrow, beam-like ribs. The deposition testimony was in conflict as to the inferences drawn from the references.

On this disputed issue, drawing reasonable inferences in favor of the non-movant, it has not been established that one skilled in the art would be motivated to select and combine features from each source in order to make the *'324* base. *Interconnect Planning, 774 F.2d at 1143, 227 U.S.P.Q. at 551* ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself").

The Decaloid Patent

The district court also referred to combination of the Decaloid base with the Marcus base. The Decaloid base has ten hollow ribs that extend to the sidewall, and ten feet [**19] between the ribs:

[*1272] [SEE FIG 2 IN ORIGINAL]

Monsanto does not explain, and we can not discern, how the combination with Marcus would have led a person of ordinary skill to the *'324* base. The court's summary holding of obviousness based on these references, separately or in combination, can not be sustained.

The Colombo Patent

The Colombo base, like the Petaloid and Decaloid bases, has hollow ribs that extend to the sidewall, in a still different structure from that of Marcus and also from that of the *'324* patent. Colombo describes his ribs as inverted U-shapes, concave, located on the outer surface of the central concavity:

[SEE FIG. 4 IN ORIGINAL]

Again, drawing reasonable factual inferences in favor of Continental, and in the absence of any suggestion or motivation in the prior art as a whole to make a selective combination of the Colombo and Marcus [*1273] structures along with other changes needed to obtain the *'324* structure, summary judgment of obviousness was inappropriate.

The district court found that there was no substantial difference between the *'324* invention and the combined teachings of the prior art:

> As obviousness can be established on the basis of the combined [**20] teachings of references, we think it is clear that simple enhancements of existing prior art, i.e. inverting the *'270* petaloid base, do not constitute a substantial difference between the subject matter claimed in the *'324* patent and that of the prior art. Thus, the facts of this case reveal no substantial difference between *'324* and the prior art.

Continental, 11 U.S.P.Q.2d at 1769 (citation omitted). However, as we have discussed, the criterion of § 103 is not whether the differences from the prior art are "simple enhancements", but whether it would have been obvious to make the claimed structure.

Objective Indicia

The district court concluded that the structure in suit is simply a variation on known themes. It is in such circumstance that the objective indicia -- the so-called secondary considerations -- are most useful to the decision-maker. The significance of a new structure is often better measured in the marketplace than in the courtroom.

Thus [HN14] when differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such [**21] objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made. *See In re Piasecki, 745 F.2d 1468, 1475, 223 U.S.P.Q. (BNA) 785, 790 (Fed. Cir. 1984)* (secondary considerations "often establish that an invention appearing to have been obvious in light of the prior art was not" (quoting *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39, 218 U.S.P.Q. (BNA) 871, 879 (Fed. Cir. 1983))).*

Continental licensed the *'324* counterpart Japanese patent to a Japanese company, Yoshino, that we are told had been unable to develop a plastic bottle for hot-fill applications. A witness for Toyo Seikan, another Japanese licensee, testified that the Conobase "sustains itself in higher temperatures, and it does not cause buckling after you fill [the bottle]", as compared with previously available plastic bottles. Continental asserts that Monsanto had been unable to develop a satisfactory bottle for hot-fill applications, and had therefore obtained this technology from Yoshino.

The district court [**22] acknowledged the commercial success of the Conobase, but stated that "we are not convinced that the Conobase *alone* accounts for any of the success." *11 U.S.P.Q.2d at 1770* (emphasis in original). The court suggested that the commercial success in Japan was due to the market strength of the Japanese licensees, and held that there is no nexus between the merits of the product and its commercial success. [HN15] It is not necessary, however, that the patented invention be solely responsible for the commercial success, in order for this factor to be given weight appropriate to the evidence, along with other pertinent factors. *See generally Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392-94, 7 U.S.P.Q.2d (BNA) 1222, 1226-28* (Fed. Cir.), *cert. denied, 488 U.S. 956, 102 L. Ed. 2d 383, 109 S. Ct. 395 (1988); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546, 221 U.S.P.Q. (BNA) 1, 7 (Fed. Cir. 1984).* Monsanto also states that the Conobase is different from the *'324* invention, so that even were the Conobase successful, this does not inure to the benefit of the *'324* patent. It is apparent that the factual issues surrounding [**23] the objective indicia were disputed, and material.

In view of the material facts requiring resolution, the issue of obviousness was not properly decided on motion for summary [*1274] judgment. We vacate the grant based on *35 U.S.C. § 103,* and remand for trial of this issue and the other issues remaining in the case.

Costs

Costs in favor of Continental.

REVERSED IN PART, VACATED IN PART, and REMANDED.

Exhibit I

Am. J. Clin. 1995; 61: 1224-30

Introduced in an amendment and response dated March 31, 2004

Acknowledged in the Office Action dated August 9, 2004

Total potentially available nucleosides of human milk by stage of lactation[1–4]

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ABSTRACT Human milk-borne ribonucleotides reportedly have important physiological roles in breast-fed infants. Previous studies measured the free nucleotide content of human milk. To more fully evaluate the physiological capacity of nucleotides in human milk, we determined the monomeric and polymeric ribonucleotide and ribonucleoside content of milk pooled from 11 American women. Subsequently, we determined the total potentially available nucleosides (TPAN) of pooled and individual milk samples segregated by stage of lactation from 100 women in three European countries to test for effect of culture and diet. The methodology simulated in vivo digestion. Polymeric ribonucleotide (primarily RNA), monomeric ribonucleotide, and ribonucleoside-containing adducts (eg, uridine diphosphate hexose) were enzymatically hydrolyzed to their constituent ribonucleosides, the preferred form for absorption. Free and enzymatically liberated nucleosides were then measured by HPLC to yield the TPAN value. The mean (± SD) TPAN concentration of the 16 pooled European samples, derived from the 100 individual samples, was 189 ± 70 μmol nucleoside/L human milk (range 82–402 μmol/L). The means (μmol/L human milk) of each nucleoside were 38 for uridine, 88 for cytidine, 31 for guanosine, and 32 for adenosine. These values included the contribution from the cellular portion of human milk. Only one of the 16 pooled samples contained a measurable amount of inosine (4 μmol/L). The potentially available ribonucleosides in the human milk samples were predominantly present as monomeric (36 ± 10%) and polymeric (48 ± 8%) nucleotides. This study demonstrates that the traditional measurement of the free nucleotide content of human milk (which accounts for neither polymeric nor cellular nucleotides) underestimates the total nucleotides available to the infant by ≥ 50%. *Am J Clin Nutr* 1995;61:1224–30.

KEY WORDS Human milk, ribonucleic acid, nucleotide, nucleoside, ribonucleoside

INTRODUCTION

Nucleotides are ubiquitous, low-molecular-weight compounds consisting of a nitrogenous base (usually adenine, cytosine, guanine, thymine, or uracil), a sugar moiety (ribose or deoxyribose), and one to three phosphate groups (1). They are essential in energy metabolism and enzymatic reactions and are the monomeric units of polymeric RNA and DNA (1). As second messengers (cAMP, cGMP) and components of cofactors (NAD, NADP, FAD), nucleotides are an integral part of carbohydrate, lipid, protein, and nucleic acid metabolism (1, 2).

Nucleotide concentrations are maintained by de novo synthesis and by a salvage pathway that recovers metabolized nucleotides and nucleosides originating from the diet or intermediary metabolism (1, 3). The two pathways are regulated by dietary availability to maintain an adequate and continuous supply of tissue nucleotides (4–6). Polymeric forms of nucleotides (DNA and RNA) are generally the primary dietary source of nucleotides (3). Polymeric nucleotides are digested by phosphodiesterases (ribonucleases and deoxyribonucleases) to nucleotides (3), which are further degraded by phosphatases to nucleosides, the preferred form for absorption in the small intestine (3, 7).

When metabolic demand exceeds the capacity for de novo synthesis, for instance, during periods of rapid growth or after injury, dietary nucleosides and nucleotides may become conditionally essential nutrients. Tests of this hypothesis in animal models have focused on tissues undergoing high rates of cellular proliferation or rapid growth, particularly the developing gut and the responsive immune system. Dietary nucleosides were reported to be important in the growth and maturation of the developing gut and to play several roles in immune function (8, 9). These roles include availability to lymphocytes unable to synthesize nucleotides (10), immune stimulation in mice when added to nucleotide-free diets (11, 12), improved response to sepsis in mice (13, 14), enhanced lymphocyte proliferation (15), stimulation of immunoglobulin production in peripheral lymphocytes (16), and increased natural killer cell activity (17).

The presence of ribonucleotides in human milk has prompted clinical research into their potential benefit for developing infants and has led to speculation as to whether they should be added to infant formula (18). The effect of dietary nucleotides on infant growth was first reported in 1963 (19). Subsequently, nucleotide supplementation reportedly altered the profile of plasma lipids and lipoproteins (20–23) and the fecal microflora (24) of formula-fed infants to be more like those of breast-fed infants; some of these claimed effects were not corroborated in other studies (25, 26). In another report, lymphocytes from infants fed nucleotide-fortified formula showed increased

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natural killer cell activity in an in vitro assay (27). Recently, nucleotide-fortified infant formula decreased the incidence of diarrhea in a group of infants of low socioeconomic status in Chile (28).

An accurate determination of the concentration and forms of ribonucleic acids in human milk is essential to evaluate their effect on outcomes of interest. Previous measurements have been nonspecific (29), or have measured only a portion of the total ribonucleic acid fraction (30, 31). Nonetheless, these data are the basis for the amount of ribonucleotide fortification in several commercial infant formulas. Because the entire polymeric ribonucleotide content of human milk has not been accurately measured, it has not been included as part of the nucleotide fortification of infant formula.

The method presented here measures all major sources of ribonucleotide in human milk potentially available for absorption and metabolism as ribonucleoside. It was first developed with a pooled, frozen sample of human milk from American women. Free nucleosides as well as those derived from nucleotides and nucleotide polymers were determined. Subsequently, several questions arose. Human milk is known to contain a significant number of cells; did the freezing and handling of the sample rupture these cells and release their nucleotide content? What was the contribution from nucleoside-containing adducts, such as uridine diphosphate glucose? Would the nucleotide concentration differ in the milk of women from other countries with diverse cultures and diets?

The present study was designed to answer these questions with an expanded sample size. Because all research on metabolically active nucleotides has been restricted to ribose-containing forms, deoxyribose forms were not considered. Henceforth, the terms nucleoside and nucleotide will refer only to ribose-containing forms.

SUBJECTS AND METHODS

For the initial method development, 11 lactating American women between 1 and 4 mo postpartum were brought to a collection center, where each completely emptied one breast under sterile conditions. These samples were immediately pooled, thoroughly mixed, divided into 10-mL aliquots, and frozen (−70 °C) until analyzed. Details of the analysis are essentially the same as those of the present study described below, except that measurement of nucleotide-containing adducts was not included.

We attempted to distinguish between cellular and noncellular pools of nucleotides during the development of the method described below using the initial sample of human milk. The concentration of polymeric and monomeric nucleotide and free nucleoside was measured in a previously frozen, deactivated, pooled human milk sample as described below. The same sample was reanalyzed after cellular disruption by high-intensity sonification (± 0.1%) (Triton X-100; Sigma, St Louis) before enzymatic hydrolysis. There was no significant increase in the concentration of polymeric and monomeric nucleotide and free nucleoside after the sonification procedure. Therefore, the measurement of the pooled and individual samples from the European human milk samples described below includes, and does not differentiate between, the cellular and noncellular pools of nucleic acids.

Subject selection

Human milk samples were collected from two sites in Italy, one in France and one in Germany. Sites were selected in these countries to address the question of the influence of differing diets and cultures on the total potentially available nucleosides (TPAN) of human milk. Subjects were selected from four stages of lactation: colostrum (through 2 d postpartum), transitional milk (3–10 d postpartum), early mature milk (1 mo postpartum), and late mature milk (3 mo postpartum). Five to seven individuals per site, per stage of lactation, contributed samples of human milk. A total of 100 individual samples were collected. Potential sample donors were contacted and the complete nature of the study described. If the potential donor expressed a willingness to participate in the study, written informed consent was obtained before collection of the sample.

Sample donors had no history of alcohol or drug abuse and had no medical condition or obstetrical complications thought to influence lactation. Donors had a singleton birth; had a hiatus of ≥ 15 mo since the cessation of breast-feeding a older child; had a preconceptional weight-for-height betwee 100% and 115% of ideal values; experienced adequate weigh gain throughout pregnancy, as determined by the investigato and gave birth after a gestation of > 36 wk. Donors were nc receiving any medication known to interfere with lactation an exclusively breast-fed their infant, ie, the infant was fed ≤ 12 mL formula/d.

Sample collection

Milk was expressed at a collection center. The mothe breast-fed the baby at midday on the same breast as the han dominance of the mother (ie, right breast for right-hande mothers). When the baby was satisfied, the mother applied a electric breast pump to the nursed breast to ensure complet emptying. Any milk collected was discarded. About 60–90 mi later, the mother washed the same breast with a mild soap an rinsed the breast repeatedly with distilled water. The breas pump was applied for ≈8 min to collect the sample while th baby suckled on the other breast to initiate let-down.

If a 50-mL sample could not be obtained in 8 min, the firs sample was immediately frozen and a second 8-min sampl was collected. Samples were collected into polyethylene con tainers labeled to indicate the donor's stage of lactation an stored at −75 °C. The frozen samples were stored at th collection site until all of the samples from that site had been collected. Frozen samples were then shipped for analysis in dry ice to the laboratory via overnight express delivery.

Sample pooling and deactivation

Application of the complete analytical scheme (four hydrolyses in duplicate) on 100 samples would have required 800 separate analyses. Because of the length of the procedure, a decision was made to pool samples at each site. The acceptability of this decision was tested by comparing 20 individual samples from one site (five at each stage of lactation) to pools of those samples at each stage of lactation. Human milk contains enzymes that can degrade nucleic acids. Treatment of the milk with strong base inactivates most interfering enzymes but does not alter concentrations of TPAN. Samples were held at −75 °C until analyzed. Samples from a single site were quickly thawed to room temperature, and aliquots of individual

samples at each stage of lactation were thoroughly mixed to provide a 20-mL sample of pooled milk. Sodium hydroxide (1 mol/L) was added (40 mL) and the samples were covered and stirred for 30–60 min. The pH of the samples was then adjusted to 7.0–7.5 with hydrochloric acid, and diluted to 100 mL with water. Five-milliliter aliquots of individual samples from one site were similarly treated (by using 10 mL sodium hydroxide and brought to 25 mL with water).

Enzymatic hydrolyses

Four distinct sample preparations were carried out in duplicate with 5 mL deactivated, diluted sample, stirred in a Pierce heating-stirring module (Reacti-Therm; Rockford, IL). An internal standard, 5-methylcytidine (30 μg; Sigma #M-6254) was added to every sample preparation. Figure 1 depicts the action of the three enzymes used in these preparations. In preparation 1, duplicate deactivated human milk samples were incubated 16–18 h with nuclease (nuclease P1 phosphodiesterase, 19 U; Sigma #N-8630) to hydrolyze polymeric to monomeric nucleotide by using a modification of the procedure described by Gehrke and Kuo (32). This was followed by incubation with pyrophosphatase (nucleotide pyrophosphatase, 0.4 U; Sigma #P-7383) to release nucleotide from adducts, and with phosphatase (bacterial alkaline phosphatase, 16 U; Sigma #P-4252) to hydrolyze nucleotide to nucleoside by using the modified procedure of Gehrke and Kuo (32) for 3 h at 37 °C. Preparation 2 included both the nuclease and phosphatase hydrolysis, preparation 3 used the phosphatase hydrolysis only, and preparation 4 was the unhydrolyzed, deactivated sample. Samples were then quantitatively transferred to 25-mL volumetric flasks with 12.5 mL 0.5 mol potassium phosphate/L, pH 10.5, and brought to the desired volume with water.

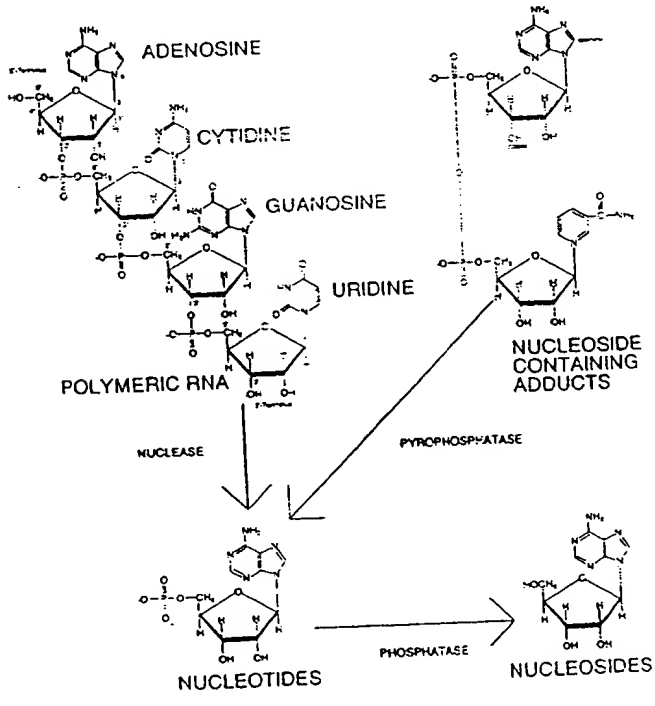

FIGURE 1. The enzymatic digestion of ribonucleotide. Polymeric RNA, and nucleoside-containing adducts (nucleoside-phosphate-phosphate-X, where X is any of a group of biologically relevant moieties, eg, NAD, UDP-glucose) are hydrolyzed to their corresponding nucleotides by the actions of nucleases and pyrophosphatases, respectively. Ribonucleotide is further hydrolyzed to nucleoside, the preferred form for absorption in the gut, by the action of phosphatases.

Solid-phase extraction

The procedure described here is based on the work of Uziel et al (33). The solid-phase extraction media was Affi-Gel 601 (#153–6101; Bio-Rad, Melville, NY). Hydrated, settled gel (150 μL) in a polypropylene microcentrifuge tube was washed twice with buffer (250 mmol potassium phosphate/L, pH 10.5) by vortexing, followed by centrifugation and removal of supernate. The washing procedure converted the gel to the basic form. A 1-mL aliquot sample from the enzymatic preparations described above was added to the gel and vortexed, binding the nucleosides to the gel. Contaminating compounds were removed from the gel-bound nucleosides by two 1-mL washings with the potassium phosphate buffer. Nucleosides were then eluted from the gel by using 750 μL 1 mol phosphoric acid/L and passed through a 0.22-μm filter directly into a vial for HPLC analysis.

HPLC analysis

The nucleosides were separated via reversed-phase, pairing chromatography on an octydecylsilane stationary column (#4M, 5314; Jones Chromatography, Lakewood, The mobile phase was 100 mmol potassium acetate/L, pH and 2 mmol hexane sulfonic acid/L (Sigma #H9026) organic modifier was acetonitrile, with an initial concent of 1%, which was linearly increased to 7% from 0 to 8 held at 7% for 2 min, and reequilibrated at 1% for 8 min b the next injection. The nucleosides were detected by a bance at 255 nm. Calibration curves for each nucleoside constructed by calculating the ratios of the area respon known concentrations of serially diluted nucleoside sta materials (Sigma products: U-3750, C-9505, I-4125, G- and A-9251) to the area of a fixed concentration of the in standard 5-methylcytidine. Linear regression gave corre coefficients > 0.9995. The sample concentration of eac cleoside was calculated by using the linear regression fo nucleoside and the area ratio (nucleoside-internal stan from analyses.

Data reduction and precision

The nucleoside concentrations measured after the four distinct sample preparations permitted determination of the amount of each nucleoside found in each form and the amount each form contributed to TPAN.

Preparation 1: Measurement of inherent free nucleosides and nucleosides resulting from nuclease, pyrophosphatase, and phosphatase hydrolysis gave the TPAN value.

Preparation 2: Hydrolysis with nuclease and phosphatase gave the amount of inherent, nucleotide-derived, and polymer-derived nucleosides. Preparation 1 − preparation 2 = nucleosides derived from nucleoside-containing adducts.

Preparation 3: Hydrolysis with phosphatase provided inherent and nucleotide-derived nucleosides. Preparation 2 − preparation 3 = polymer-derived nucleoside.

Preparation 4: No enzymatic hydrolysis yielded inherent nucleosides. Preparation 3 − preparation 4 = nucleotide-derived nucleoside.

Preliminary computations demonstrated that the SD was proportional to the mean. Therefore, the percent relative SD (% RSD) for each duplicate was a more appropriate estimate of the variability of the measurement than the SD.

Overfortification recoveries

An aqueous TPAN-fortified solution was prepared that contained ribonucleosides, 5'-mononucleotides, polymeric yeast RNA, and nucleoside-containing adducts (uridine diphosphate glucose, cytidine diphosphate choline, guanosine diphosphate mannose, and NAD), all at concentrations 100 times those typical for human milk. An aliquot was diluted 1:100 with water and hydrolyzed for 16 h in 0.2 mol potassium hydroxide/L to quantitatively cleave all of the polymeric RNA to 2'- and 3'-mononucleotides. The pH of this solution was adjusted to ≈9 with hydrochloric acid and incubated with alkaline phosphatase and nucleotide pyrophosphatase to hydrolyze all nucleotide and nucleoside-containing adducts to nucleoside, and the nucleoside concentrations were measured directly (without solid-phase extraction). Because previous work (data not shown) demonstrated that the phosphatase- and pyrophosphatase-catalyzed reactions were quantitative, this alkaline and enzymatic hydrolysis and HPLC analysis was used to define theoretical concentrations. The TPAN-fortified solution was diluted 1:100 with one of the pooled human milk samples (early mature milk from site 3, Italy) and the TPAN analysis carried out to determine recovery.

RESULTS

When the difference between the fortified and unfortified pooled sample is compared with the concentration derived from the alkaline enzymatic hydrolysis of the fortified solution, 91% of the theoretical TPAN value was recovered (Table 1). The method recovered within 5% of the "actual" value for cytidine and adenosine and underestimated the uridine value by ≈12% and the guanosine value by ≈24%. The %RSD of the measurement of each of the four nucleosides and the TPAN value is an indicator of the precision of the measurement (Table 1). The variance of the method makes only a very small contribution to the between-sample variance in this study.

Table 2 provides a summary of all TPAN data by site and by stage of lactation. Comparison between sites at each stage of lactation shows considerable variability. The mean ranges of TPAN values (μmol/L) from the different sites were 82–164 (colostrum), 144–210 (transitional milk), 172–402 (early mature milk), and 156–259 (late mature milk). Comparison between stages of lactation at each site shows equal variability in TPAN (μmol/L): 146–172 at site 1, 82–219 at site 2, 164–214 at site 3, and 150–402 at site 4. The mean TPAN (sites combined) was lowest in colostrum (137 μmol/L) but showed no consistent upward or downward trend in transitional milk (177 μmol/L), early mature milk (240 μmol/L), or late mature milk (202 μmol/L). Also shown in Table 2, the mean TPAN (excluding adducts) from pooled American milk (161 μmol/L) was within the range of the European milk (82–402 μmol/L).

The percentage of each form of the mean TPAN for the entire European pool is provided in Table 3. Most of the TPAN was present as polymeric (48 ± 8%; $\bar{x}$ ± SD) and monomeric

TABLE 1
Accuracy and precision of the total potentially available nucleosides (TPAN) method

Test samples	Uridine	Cytidine	Guanosine	Adenosine	TPAN
TPAN-fortified (μmol/L)[1]	64	70	73	69	276
Pooled milk (μmol/L)	67	146	91	97	402
Pooled milk + TPAN-fortified (μmol/L)	124	219	147	165	654
Difference (μmol/L)	57	73	55	67	252
Percent recovery (%)[2]	88	104	76	98	91
Precision of TPAN method					
Relative standard deviation (%RSD)[3]	3.6	2.0	2.0	2.0	1.9

[1] An aqueous solution of nucleosides, monomeric and polymeric nucleotides, and nucleoside-containing adducts at concentrations found in human milk, and subjected to alkaline and enzymatic hydrolysis to yield theoretically accurate concentrations.

[2] Difference between the fortified and unfortified pooled milk sample divided by the concentrations measured in the TPAN-fortified solution.

[3] Computed from 16 degree-of-freedom estimate of the variance.

TABLE 2
Nucleotide and total potentially available nucleoside (TPAN) in pooled human milk by stage of lactation[1]

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
			μmol/L		
Colostrum					
Site 1	27	84	22	20	155
Site 2	21	33	15	13	82
Site 3	30	82	26	26	164
Site 4	24	84	20	22	150
Mean	26	71	21	21	137
Transitional milk					
Site 1	23	82	22	19	146
Site 2	33	76	19	17	144
Site 3	37	84	43	42	206
Site 4	36	100	36	38	210
Mean	32	86	30	29	177
Early mature milk					
Site 1	30	86	28	28	172
Site 2	50	79	23	21	173
Site 3	44	96	36	37	214
Site 4	67	146	91	97	402
Mean	48	102	45	46	240
Late mature milk					
Site 1	36	73	22	25	156
Site 2	58	106	29	27	219
Site 3	49	81	20	24	173
Site 4	45	124	40	49	259
Mean	47	96	28	31	202
Grand Mean	38	88	31	32	189
SD	13	24	18	20	70
Range	21–67	33–146	19–92	13–97	82–402
American pool[2]	37	70	30	24	161

[1] The data are from 100 individual samples collected at four sites and combined into 16 pooled samples (5–7 individual samples per site per stage of lactation). Site 1, Rouen and Mount Saint Aignau, France; Site 2, Mainz, Germany; Site 3, Bolzano, Italy; Site 4, Treviso, Italy.

[2] A pooled sample of milk collected from 11 American women between 2 and 4 mo postpartum.

TABLE 3
Percentage of total potentially av[illegible]ucleosides (TPAN) in pooled human milk as adducts, polymeric nucleotides, monomeric nucleotides, and nucleosides[1]

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
			% of total		
Polymeric nucleotides	19 ± 7	57 ± 12	59 ± 21	47 ± 11	48 ± 8
Monomeric nucleotides	36 ± 12	37 ± 13	34 ± 14	35 ± 10	36 ± 10
Nucleosides	18 ± 14	5 ± 5	1 ± 2	5 ± 4	8 ± 6
Adducts[2]	27 ± 12	1 ± 1	7 ± 15	13 ± 9	9 ± 4

[1] $\bar{x}$ ± SD. Based on the mean of the entire pool of human milk collected from 100 individuals at four stages of lactation at four sites.

[2] Adducts are of the form nucleoside-phosphate-phosphate-X, where X is a biologically relevant moiety, for example, uridine diphosphate galactose or NAD.

(36 ± 10%) nucleotide. Nucleosides (8 ± 6%) and nucleotide from adducts (9 ± 4%) were a small but significant contribution. Monomeric and polymeric nucleotides were also the predominant forms of TPAN in the pooled sample of American milk (data not shown) accounting for 93% of the total (excluding adducts).

The distribution of individual nucleotides in each fraction is also shown in Table 3. Uridine was found in all fractions, but primarily as free nucleotide (36 ± 12%) and adduct (27 ± 12%). Cytidine, guanosine, and adenosine were mostly in the polymeric and monomeric nucleotide fractions.

To demonstrate the acceptability of the decision to pool samples, comparisons were made between pooled sample values to the mean values of the five individuals contributing to those pools at site 3 (Italy). The concentrations of individual nucleosides and the TPAN values of the pooled samples and the means of the individuals in the pools at each stage of lactation are given in Table 4. At every stage of lactation, both for individual nucleosides and for TPAN, the measured value of the pooled sample is virtually identical to the mean of the five individual samples that formed that pool.

DISCUSSIO[illegible]

The recovery of adenosine and cytidine from human milk samples (Table 1) appeared to be accurate within 5%. Although the measurement of uridine and guanosine was less accurate, all analyses had high precision. Previous work in this laboratory indicated that the underestimation of guanosine, and probably of uridine, is the result of incomplete elution of these nucleosides from the solid-phase extraction media (boronate derivitized gel). Incomplete enzymatic liberation of the guanosine residues or a contaminating degradative activity that acts on guanosine could also contribute to its underestimation. The TPAN method recovers between 90% and 95% of the true TPAN value, while slightly underestimating the uridine content, and significantly underestimating the guanosine content.

This study answered the questions raised by the preliminary work, and confirmed and extended those data. The failure to detect any increase in TPAN in human milk after cellular disruption by high-intensity sonication indicates that the nucleotide content of the cells present in human milk was accounted for in the TPAN analysis. The procedure by which milk samples were collected, frozen, thawed, and deactivated l[illegible] ment with strong base apparently resulted in complete c[illegible] before the analysis.

The addition of nucleotide pyrophosphatase treatme[illegible] TPAN analysis permitted estimation of the nucleotides from nucleotide-containing adducts. Overall this repre[illegible] ± 4% of the TPAN value (Table 3), a small but sig[illegible] addition, because the adducts accounted for a good pc[illegible] the human milk uridine (27 ± 12%). The work of Ru[illegible] al (10), Van Buren et al (12), Kulkarni et al (13), and l[illegible] et al (14) suggests that uridine may account for muc[illegible] immunological effects attributed to nucleotides.

Most importantly, these data show a wide range of[illegible] trations of four individual nucleosides as well as the T[illegible] these 16 pooled samples, representing 100 individual[illegible] of human milk. Ranges for the entire pool (Table [illegible] 21–67 μmol uridine/L, 33–146 μmol cytidine/L, 19–9[illegible] guanosine/L, and 13–97 μmol adenosine/L, for an[illegible] range of 82–402 μmol TPAN/L. Cytidine was consiste[illegible] nucleotide in greatest concentration (88 ± 24 μmol/[illegible]

TABLE 4
The total potentially available nucleosides (TPAN) of pooled samples compared with individual human milk samples[1]

	Uridine	Cytidine	Guanosine	Adenosine	TPAN
			μmol/L		
Pooled colostrum sample mean	30	82	26	26	164
Mean of samples in pool (n = 5)	29	81	27	27	169
Range of individual samples	17–39	23–144	11–51	17–46	83–253
Pooled transitional milk mean	37	84	43	42	206
Mean of samples in pool (n = 5)	35	85	43	42	214
Range of individual samples	16–61	43–123	10–91	17–86	88–378
Pooled early mature milk mean	44	96	36	37	214
Mean of samples in pool (n = 5)	44	92	35	37	215
Range of individual samples	23–61	61–129	18–80	20–77	126–357
Pooled late mature milk mean	49	81	20	24	173
Mean of samples in pool (n = 5)	47	79	19	23	171
Range of individual samples	23–113	50–108	5–41	6–54	90–325

[1] Pooled samples consisted of individual samples from 20 women (5 per stage of lactation).

MJ. Leach 24.5 45.2 14.1 18.7

MJ. Enfamil sample mg/L 11

uridine was consistently found in greatest concentrations as adduct (27 ± 12%) and free nucleoside (18 ± 14%). In the comparison between pooled and individual samples from site 3 (Italy), there was excellent agreement between the mean concentrations of the individual samples and the concentration of the pooled sample to which they contributed. However, there was a wide range of values among the samples at all sites over the course of lactation and at any given stage of lactation.

In answer to our third question, this sample-to-sample variability appears to be a property of human milk and not a function of the measurement or stage of lactation. If one assumes that diet varies with nationality, maternal diet also was not a factor. The collection method was well standardized and should not have been a source of variability. Concentrations in colostrum were somewhat lower than the other types of milk, and purine concentrations were generally lower and varied more than the pyrimidine concentrations. However, there was no consistent relation between TPAN concentration, stage of lactation, or country in which the women resided for the European milk samples. The concentration of polymeric and monomeric nucleotides and nucleosides, and the relative proportions of individual nucleosides in the pooled sample of milk from American women were similar to the values in samples of milk from European women (Table 2).

Although there was variability in TPAN among the pooled samples, the percentage of the total contributed by each form was more constant. The nucleotides in these samples were predominantly present as monomeric and polymeric nucleotides. The sum of these two forms ranged from 72% to 92% of the total in the 16 pooled samples with an average of 84%. Consistently, only low concentrations of nucleosides were present, with uridine predominating. Slightly higher concentrations of nucleoside-containing adducts were also present, again with uridine derivatives predominant. Similar relations between the amounts of RNA, nucleotide, and nucleoside were found in the pooled sample of milk from American women (data not shown).

Earlier reports of the nucleotide content of human milk have either described only the monomeric portion or total RNA. Furthermore, previous measurements of RNA in human milk have been less specific or comprehensive. Typical of the nonspecific measurements was a report by Sanguansermsri et al (29) of RNA concentrations in human milk of ≈300–1800 μmol/L. The method of analysis did not involve selective isolation of the nucleic acid fraction before measurement. In addition, the actual measurement procedure was nonspecific and prone to overestimation in complex sample matrixes. More specific and accurate measurements of some forms of ribonucleic acids have been reported. Janas and Picciano (30) measured via HPLC the concentration of mono- and diphosphate nucleotides in human milk during 3 mo of lactation. Gil and Sanchez-Medina (31) reported concentrations for mononucleotides and included many nucleoside-containing adducts (eg, uridine diphosphate hexose and guanosine diphosphate mannose). Neither of these studies of specific forms of nucleotides provided an assessment of the total concentration presumably available in vivo on digestion.

Our data agree well with the previous reports of specific components of the monomeric nucleotide fraction of human milk. When the mean of the 16 pooled samples and the average percentages as nucleotide are used, there are 14 μmol uridine nucleotide/L, 33 μmol cytidine nucleotide/L, 10 μmol guanosine nucleotide/L, and 11 μmol adenosine nucleotide/L for an average total of 68 μmol nucleotides/L and a range of 39–161 μmol nucleotides/L. This measurement does not distinguish between and includes contribution from mono-, di-, and triphosphonucleotides. Janas and Picciano (30) measured mono- and diphosphonucleotide concentrations and reported mean values of 10 μmol uridine nucleotide/L, 27 μmol cytidine nucleotide/L, 6 μmol guanosine nucleotide/L, and 7 μmol adenosine nucleotide/L, for a total of 56 μmol nucleotide/L (including inosine monophosphate).

Janas and Picciano (30) measured inosine monophosphate at various stages of lactation, and the range of their reported values was 1.5–18.4 μmol/L with an average of 6.5 μmol/L. In the present study, inosine derivatives could only be found in 1 of the 16 pooled samples (4 μmol/L in a sample containing 402 μmol TPAN/L) and detected at trace concentrations (> 1 μmol inosine derivative/L milk) in eight others. But 7 of the 16 pooled samples did not contain detectable inosine concentrations. Previous results (data not shown) indicated that human milk contains adenosine deaminase activity (ADA) and that adenosine added to a human milk sample in which ADA had not been deactivated could be partially recovered as inosine. We therefore believe that the presence of inosine in an analysis of human milk may be a sample-preparation artifact. In that regard, the highest concentration of inosine that could be measured represented only 1% of the total of that sample.

Gil and Sanchez-Medina (31) also measured individual nucleotide concentrations, which agree well with this study's determination. In addition, they measured guanosine diphosphate mannose concentrations and found ≈5 μmol/L at various stages of lactation. The average result for adduct-derived guanosine in the present study was ≈2 μmol/L and ranged from not detectable to ≈11 μmol adduct-derived guanosine/L. Gil and Sanchez-Medina (31) also measured uridine diphosphate hexosamine plus uridine diphosphate hexose concentrations, which ranged from ≈5 to > 30 μmol/L. In the present study ≈10 μmol uridine adduct/L was measured, with a range from <1 to ≈21 μmol uridine adduct/L.

There is continued interest among clinical researchers in the field of infant nutrition and some regulatory agencies to accurately determine the amount of ribonucleotides in human milk for use in infant formula. The in vitro enzymatic digestion of the method described here approximates in vivo digestion (Figure 1). Monomeric nucleotides were obtained by the digestion of RNA and nucleoside-containing adducts (a nucleoside-containing adduct is of the general formula nucleoside-phosphate-phosphate-X, where X is any of a group of biologically relevant moieties). Liberated and inherent mononucleotides were further digested to nucleosides, the preferred form for absorption in the gut (3, 7). The subsequent extraction with a boronate derivitized support and separation via HPLC allowed accurate measurement of isolated uridine, cytidine, inosine, guanosine, and adenosine. Measurement of the inherent free nucleosides followed by sequential application of the three enzymatic hydrolyses allowed estimation of the TPAN as polymeric nucleoside (RNA), nucleotide, nucleoside, and nucleoside-containing adduct, and the percentage of each nucleoside present. This complete enzymatic hydrolysis and measurement of the entire nucleotide fraction of human milk is a reasonably accurate reflection of the in vivo process: ie, TPAN.

These data suggest that if there is a need for the addition of nucleotides to infant formula, substantially larger amounts than are currently used would be required to achieve the average TPAN concentration in human milk.

We give special thanks to Vickie Pound and Norman White for their exceptional dedication, diligence, and the high quality of their work in the performance of this study.

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Exhibit J

Ex parte Levy, 17 USPQ2d 1461 (BPAI)

Introduced in an amendment and response dated March 31, 2004

Acknowledged in the Office Action dated August 9, 2004

*1990 Pat. App. LEXIS 18, *; 17 U.S.P.Q.2D (BNA) 1461*

Ex parte Stanley B. Levy

Appeal No. 90-1864 from Art Unit 158.

Application filed December 21, 1988, Serial No. 287,234, which is a Division of Serial No. 914,108, filed October 1, 1986, now RE 32,983 granted July 4, 1989; and a Reissue of Serial No. 510,812, filed July 5, 1983, now Patent No. 4,490,421, granted December 25, 1984.

Balloon and Manufacture Thereof.

Board of Patent Appeals and Interferences

1990 Pat. App. LEXIS 18; 17 U.S.P.Q.2D (BNA) 1461

July 18, 1990, Heard
October 16, 1990, Decided

CORE TERMS: balloon, biaxially, oriented, catheter, examiner, blow molding, injection, disclose, polymeric, terephthalate, polyethylene, plastic, expander, skill, supplied, column, stretching, inherently, inherency, invention, declaration, inelastic, synthetic, container, producing, viscosity, beverage, stretch, bottle, tensile strength

[*1]

Before Steiner, Tarring and J. Smith, Examiners-in-Chief.

COUNSEL:
Louis H. Rombach et al. for appellant.

Primary Examiner - James Seidleck.
Louis H. Rombach et al.
E. I. DuPont De Nemours and Co.
Legal Department
Patent Division
Wilmington, Delaware 19898

OPINIONBY: STEINER

OPINION:
Steiner, Examiner-in-Chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting

sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

13. High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).

25. High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation **[*2]** catheter balloon.

The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309 May 15, 1973
Schjeldahl et al. (Schjeldahl '989)	4,413,989 Nov. 8, 1983 n1
Schjeldahl et al. (Schjeldahl '000)	4,456,000 June 26, 1984 n2

n1 Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

n2 See footnote 1.

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. 102.

The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. In re Spada, F.2d , 15 USPQ2d 1655 (Fed. Cir. 1990); In re Bond, F.2d , 15 USPQ2d 1566 (Fed. Cir. 1990); Diversitech Corp. **[*3]** v. Century Steps, Inc., 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); Alco Standard Corp. v. TVA, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); In re Marshall, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); In re Arkley, 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a prima facie basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. 102, the examiner is obliged to point out where Schjeldahl discloses a biaxially oriented polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states

the reference clearly teaches **[*4]** a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

arguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is clearly stated in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

(A) an expander n3 formed from a thin, flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material (column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

n3 Schjeldahl characterizes the catheter balloon as an expander.

(b) The expander 30 is preferably formed from a suitable synthetic plastic material, such as biaxially oriented polypropylene, by an injection blow molding operation and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in **[*5]** the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);

(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);

(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);

(e) the expander 30 is formed from a biaxially oriented thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);

(f) the expander 82 is preferably formed from a suitable synthetic plastic material such as biaxially oriented polypropylene or biaxially oriented polyethylene terephthalate by an injection molding operation and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and

(g) Apparatus as in claim 1 wherein said nonelastic expander **[*6]** member comprises a longitudinally extending thin, flexible, tubular element formed from a biaxially oriented synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis

supplied).
These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the starting material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The final article, i.e., the expander or catheter balloon, is not characterized as biaxially oriented. Moreover, it would appear to be undisputed that the only method disclosed by Schjeldahl for transforming the biaxially oriented starting plastic into the final catheter balloon, i.e., injection blow molding, is not capable of producing a biaxially oriented catheter balloon. In fact, it is undisputed that injection blow molding would destroy the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits **[*7]** V, VI and VIII, n4 which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. n5

n4 Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

n5 We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. In re Weber, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); In re Michalek, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made of a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, i.e., whether the catheter balloon disclosed by Schjeldahl is inherently biaxially oriented.

Indeed, the examiner agrees with appellant's position that injection blow molding could not produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

statements that **[*8]** injection blow molding without stretching will not produce a biaxially oriented article are true . . . (emphasis supplied).

The examiner goes on, in the same sentence, to state:

but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory

equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a prima facie basis to deny patentability to a claimed invention rests upon the examiner. In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner **[*9]** must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); Hansgirg v. Kemmer, 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have only a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would not have produced a biaxially oriented balloon and would have destroyed the biaxial orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the **[*10]** conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) necessarily means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are inconsistent with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

> the membrane equation used to determine the tensil [sic], [tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

> certainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration **[*11]** would be reasonable.

As noted above, the conflicting results obtained by applying the membrane equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction necessarily means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We

do not find a sufficient basis to support the determination that Schjeldahl's balloon is inherently (necessarily) biaxially oriented. In re King, supra; W.L. Gore & Associates, Inc. v. Garlock, Inc., supra; **[*12]** In re Oelrich, supra; In re Wilding, supra; Hansgirg v. Kemmer, supra. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. 102 as anticipated by Schjeldahl is reversed. n6

n6 There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000 - 40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

The Rejection of Claims 13 through 17 under 35 U.S.C. 103 Based upon the Combined Disclosures of Schjeldahl **[*13]** and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; e.g., at least about 0.85.

It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth solely for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic], [examiner's] inherency arguments. n7

. . . The examiner is not substituting the process of Wyeth **[*14]** et al into Schjeldahl et al since both disclose the same process. n8 Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

n7 Actually, according to the Final Rejection which is incorporated in the Answer,

it is the Examiner's position that it would be prima facie obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

n8 It is apparent from our reversal of the examiner's rejection under 35 U.S.C. 102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, arguendo, the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. 103 must fall **[*15]** because the examiner has not established that the resulting catheter balloon is biaxially oriented. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. 103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer, n9 we are constrained to address that issue.

n9 The noted statement provides:

Certainly in the least there was an invitation to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

There appears to be no dispute that one having ordinary skill in the art would have recognized **[*16]** the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, the technique employed by Wyeth to produce a beverage container. See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, Wyeth disagrees. See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could not be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the **[*17]** affidavits of Rydell, Pinchuk and Kaufman, n10 that the known processes for producing biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. n11 Based upon the record before us, it would appear unrealistic to

conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a reasonable expectation of obtaining a biaxially oriented polymeric catheter balloon. In re O'Farrell, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The rejection under 35 U.S.C. 103 is also reversed.

n10 We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

n11 We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated

as a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that

anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures -- they are both fluid containers. **[*18]**

REVERSED

Exhibit K

In re Carleton, 599 F.2d 1021 (CCPA 1979)

Introduced in a response dated November 16, 2004

Acknowledged in the Office Action dated December 27, 2004

LEXSEE 202 USPQ 165

IN THE MATTER OF THE APPLICATION OF PETER S. CARLETON

Appeal No. 78-634.

United States Court of Customs And Patent Appeals

599 F.2d 1021; 1979 CCPA LEXIS 241; 202 U.S.P.Q. (BNA) 165

June 7, 1979, Decided

PRIOR HISTORY: [**1]

Serial No. 563,464.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant patent applicant sought review of decision of the Patent and Trademark Office Board of Appeals, which affirmed the patent examiner's rejection of appellant's patent claims under *35 U.S.C.S. § 103* for a chemical process in the production of hydroquinone.

OVERVIEW: Appellant, a patent applicant for chemical process producing hydroquinone, sought review of the Board's decision affirming the patent examiner's rejection of appellant's patent claims under *35 U.S.C.S. § 103*. The Board held that cited references made out a strong case of prima facie obviousness against appellant. The starting material of the claimed process was encompassed in a prior art's generic starting materials, and an oxidation agent in the claimed process was stated in a prior art to be the preferred oxidizing agent. Appellant rebutted the rejection with affidavits disclosing test results that showed substantially lower yields of hydroquinone obtained in using appellant's starting material than the yield obtained with the prior art's starting material. It would not have been obvious to use an oxidizing agent in the claimed process together with the starting material in the claimed process. The court reversed, holding that appellant's affidavits, together with the other evidence, sufficed to rebut the prima facie case of obviousness.

OUTCOME: The court reversed the Board's decision.

LexisNexis(R) Headnotes

Patent Law > Nonobviousness > Evidence & Procedure > Prima Facie Obviousness
Patent Law > Nonobviousness > Evidence & Procedure > Presumptions & Proof
Patent Law > Inequitable Conduct > General Overview
[HN1] In a *35 U.S.C.S. § 103* case, the burden of proof is on the Patent and Trademark Office to establish a prima facie case of obviousness, and, once this has been accomplished, the burden of going forward with evidence to rebut that prima facie case is shifted to the applicant.

Patent Law > Nonobviousness > Evidence & Procedure > Prima Facie Obviousness
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Infringement Actions > Burdens of Proof
[HN2] Whether a prima facie case under *35 U.S.C.S. § 103* is "strong" or "weak" is not material. If the patent applicant presents rebuttal evidence, the decisionmaker must consider all of the evidence of record, both that supporting and that rebutting the prima facie case, in determining whether the subject matter as a whole would have been obvious.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
Patent Law > Nonobviousness > General Overview
[HN3] The issue on appeal of a finding of obviousness under *35 U.S.C.S. § 103,* is whether the decision of the Patent and Trademark Board of Appeals is clearly erroneous.

Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > U.S. Patent & Trademark Office Proceedings > Appeals
[HN4] Obviousness under *35 U.S.C.S. § 103,* is a legal conclusion based on factual evidence and not a factual determination. Therefore, the proper issue before a reviewing court is whether the Patent and Trademark Board of Appeals erred, as a matter of law, in holding that the claims were properly rejected under *35 U.S.C.S. § 103.* In deciding this issue, the court will make an independent determination as to the legal conclusions and inferences which should be drawn from the findings of fact.

Patent Law > U.S. Patent & Trademark Office Proceedings > Appeals
Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN5] In deciding whether the Trademark and Patent Office Board of Appeals erred, as a matter of law, in holding that claims were properly rejected under *35 U.S.C.S. § 103,* by the Patent and Trademark Office examiner, the court must make an independent determination as to the legal conclusions and inferences which should be drawn from the findings of fact.

Patent Law > Nonobviousness > Evidence & Procedure > Prima Facie Obviousness
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > U.S. Patent & Trademark Office Proceedings > Appeals
[HN6] Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

COUNSEL:

Roman Saliwanchik, attorney of record, for appellant, *Denis A. Firth, John Kekich,* of counsel.

Joseph F. Nakamura for the Commissioner of Patents, *Fred W. Sherling,* of counsel.

OPINIONBY:

MILLER

OPINION: [*1021]

Before MARKEY, Chief Judge, RICH, BALDWIN, and MILLER, Associate Judges, and KUNZIG, * Judge.

* The Honorable Robert L. Kunzig, Judge, United States Court of Claims, sitting by designation.

MILLER, Judge.

This is an appeal from the decision of the Patent and Trademark Office ("PTO") Board of Appeals ("board") sustaining the rejection under *35 USC 103* of claims 9-13 and 15-16. We reverse.

BACKGROUND

The Invention

Appellant's application n1/ discloses a process for the substantially quantitative production of hydroquinone. Claims 9-10 and 15 n2/ are directed to the reaction of p-isopropenylphenol and hydrogen peroxide in an inert solvent such as glacial acetic acid and in the presence of a catalytic amount of a strong mineral acid to produce hydroquinone and acetone (see reaction step (3) [*1022] below). Claims 11-13 and 16 n3/ are directed to the semicontinuous production of hydroquinone through the production [**2] of p-isopropenylphenol from phenol and acetone, according to the following reaction sequence: [See illustration in original.]

n1 Serial No. 563,464, filed March 31, 1975, for "Process."

n2/ Claim 9, which is illustrative of this set of claims, reads:

9. A process which comprises reacting p-isopropenylphenol with an at least equimolar amount of hydrogen peroxide in the presence of

glacial acetic acid and a catalytic amount of a strong acid selected from the group consisting of sulfuric, phosphoric, p-toluenesulfonic, benzenesulfonic, methanesulfonic and ethanesulfonic acids, said reaction being carried out at a temperature not greater than 80 degree C whereby there is obtained hydroquinone and acetone.

n3/ Claim 12, which is illustrative of this set of claims, reads:

12. A semicontinuous process for the conversion of phenol to hydroquinone which comprises condensing phenol and acetone in the presence of acid to obtain Bisphenol A, subjecting said Bisphenol A to alkaline hydrolysis to yield a mixture of phenol and p-isopropenylphenol subjecting said mixture of phenol and p-isopropenylphenol, without separation, to reaction with at least an equimolar amount, based on p-isopropenylphenol, of hydrogen peroxide in the presence of an inert solvent and a catalytic amount of a strong acid selected from the group consisting of sulfuric, phosphoric, p-toluenesulfonic, benzenesulfonic, methanesulfonic and ethanesulfonic acids said reaction being carried out at a temperature not greater than 80 degree C, to obtain a mixture of hydroquinone, phenol, and acetone, recovering the hydroquinone therefrom, and recovering the phenol and acetone generated as by-products for re-use as starting materials in a subsequent cycle of the above steps. [**3]

The Rejections and Appellant's Response

The examiner rejected claims 9-10 and 15 as unpatentable over a patent to Robert H. Saunders ("Saunders"), n4/ which discloses a process for the preparation of various phenols from Alpha, Beta-unsaturated alkyl-substituted aryl n5/ compounds. Hydroquinone is a phenol. n6/ His reaction occurs in a liquid solvent, such as acetic acid, with a strong acid catalyst and, preferably, with "low cost" hydrogen peroxide as the oxidizing agent. In example 2, Alpha-methylstyrene, which the examiner said is the closest in structure to the starting material of appellant's claimed invention (p-isopropenylphenol), is reacted with t-butylhydroperoxide to produce phenol in about an 80% yield: [See illustration in original].

Although the production of hydroquinone as such is mentioned by Saunders, the only suggested process begins with , , ', '-tetramethyl-p-xylylene dialcohol as the starting material. n7

n4 U.S. Patent No. *2,44,014*, issued June 30, 1953, for "Phenol Production."

n5 The patent defines the term "aryl" to include the "phenyl" radical.

n6 A phenol is a benzene ring to which a hydroxyl group (-OH) has been attached: [See illustration in original].
Other substituents (or groups) may be attached to the benzene ring at various points around the ring. Hydroquinone is within the class of phenols because it has an additional hydroxyl group attached to the benzene ring: [See illustration in original].

n7. The process would be represented as follows: [See illustration in original]. [**4]

The examiner's rejection of claims 11-13 and 16 was based on Saunders in view of a patent to John L. Jones ("Jones"). n8 Jones was cited for the disclosure of a method for the preparation of phenols having unsaturated substituents (such as p-isopropenylphenol--the starting material of claims 9-10 and 15) via a two-step reaction. In the first step, a phenol is condensed in the presence of an acid catalyst with a ketone to produce an intermediate "condensation product," which is then treated with a strong alkali metal base to neutralize the acidic catalyst. The mixture undergoes pyrolysis producing the desired phenolic compound (with an unsubstituted side chain), [*1023] phenol, and a polymeric residue. On appeal, appellant has not argued that the first two steps of his reaction sequence, in which p-isopropenylphenol is produced, would not have been obvious in light of the PTO's citation to Jones. n8

n8 U. S. patent No. *2,497,503*, issued February 14, 1950, for "Preparation of Substituted Phenols."

In response to the rejections, appellant submitted several affidavits (including two by him) under *37 CFR 1.132*. One by Sheng-Hong A. Dai described two tests. In the first test [**5] ("Dai I"), the procedure of example 2 of the Saunders patent was followed "exactly" n9 (the starting material being -methylstyrene), except the hydrogen peroxide (instead of t-butylhydroperoxide) was used as the oxidizing agent. A yield of only 15.8% phenol was reported; the major product was believed to be dimers of the -methylstyrene. n10 In the second test ("Dai II"), the "exact" reaction conditions of example 2 of Saunders were followed except that p-isopropenylphenol (the starting material of appellant's process) was used. A yield of only 47% hydroquinone was obtained.

n9 A miscalculation in the original Dai affidavit was corrected before the board's opinion on reconsideration, thereby alleviating the board's concern in its original opinion that an excessive amount of sulfuric acid was used in Dai I.

n10 Although conditions were somewhat varied from those of the Saunders reference, the first affidavit of appellant Carleton ("Carleton I") reports the result of a similar experiment. No phenol was detected, and the major products were a dimer of -methylstyrene and 1,1,3-trimethyl-3-phenylindan.

Appellant also directed the examiner's attention to a published German [**6] application, n11/ which discloses a process for the production of hydroquinone from 1,4-diisopropenylbenzene n12/ in the presence of glacial acetic acid as the solvent, either mineral acids or Friedel-Crafts type compounds as the catalyst, and hydrogen peroxide as the oxidizing agent. The pertinent examples indicate yields of hydroquinone of about 10-35%. n13/

n11/ German patent application No. S33,841 (now patent No. 947,308), filed June 12, 1953, by Societe des Usines Chimiques Rhone-Poulenc and published on February 23, 1956.

n12/ 1,4-diisopropenylbenzene has the following structure: [See illustration in original.]

n13/ The second affidavit of appellant ("Carleton II") reports an experiment similar to those of the German application in which 1,4-diisopropenylbenzene was also the starting material. A yield of about 28% of hydroquinone was obtained.

The Decision Below

The board found that the cited references "make out a strong case of prima facie obviousness" against appellant's claims, because (1) the starting material of the claimed process is encompassed in Saunders' generic starting materials; (2) the oxidizing agent in the claimed process (hydrogen peroxide) [**7] is stated by Saunders to be the preferred peroxide (due to its low cost); and (3) Saunders and Jones disclose all of the other reaction conditions. It further found that the disclosure of hydroquinone production by the Saunders process, "albeit from a different starting material than the one recited in appellant's claims, would lead one of ordinary skill to expect that the presence of the first formed hydroxyl group [on the benzene ring] would not interfere with the process of forming the second hydroxyl group." The board said the affidavit evidence was unpersuasive and concluded that the Carleton I and II affidavits failed to follow the prior art closely enough. It particularly criticized the concentration of the reactants and catalysts and the short reaction times.

On reconsideration, the board adhered to its original decision, saying that the affidavits merely indicate that it is possible to operate within the teachings of Saunders without obtaining a good yield. It also said that the Dai II result conflicts with the result in example 9 of appellant's specification, illustrating that there can be considerable variation in yield from "minor modification in reaction conditions." [**8]

OPINION

We do not agree with the board's characterization of the showing made by [*1024] the examiner as a "strong" prima facie case. [HN1] In a *35 USC 103* case, the burden of proof is on the PTO to establish a prima facie case of obviousness, *In re Warner, 54 CCPA 1628, 379 F.2d 1011, 154 USPQ 173 (1967)*, cert. denied, *389 U.S. 1057 (1968)*, and, once this has been accomplished, the burden of going forward with evidence to rebut that prima facie case is shifted to the applicant. *In re Murch, 59 CCPA 1277, 464 F.2d 1051, 175 USPQ 89 (1972); In re Hyson, 59 CCPA 782, 453 F.2d 764, 172 USPQ 399 (1972)*. [HN2] Whether a prima facie case is "strong" or "weak" is not material. If the applicant presents rebuttal evidence, the decisionmaker must consider all of the evidence of record (both that supporting and that rebutting the prima facie case) in determining whether the subject matter as a whole would have been obvious. n14/ *In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Lewis, 58 CCPA 1270, 443 F.2d 389, 170 USPQ 84 (CCPA 1971)*. The correct procedure for considering rebuttal evidence was set forth by this court in *In re Rinehart, supra at 1052, 189 USPQ at 147:*

n14/ The Solicitor's brief states that "the [HN3] issue is whether the decision of the Board of Appeals was clearly erroneous." However, "obviousness [HN4] is a legal conclusion based on factual evidence, *Graham v. John Deere Co., [383 U.S. 1, 148 USPQ 459 (1966)]*... and not a factual determination." *In re Warner, 54 CCPA 1628, 1634 n.6, 379 F.2d 1011, 1016 n.6, 154 USPQ 173, 177 n.6 (1967)*. [HN5] Therefore, the proper issue before us is whether the board erred, as a matter of law, in holding that the claims were properly rejected under *35 USC 103*. In deciding this issue the court will make "an independent determination as to the legal conclusions and inferences which should be drawn from... [the findings of fact]." See *United States v.*

Mississippi Valley Generating Co., 364 U.S. 520, 526 (1961).

[**9]
Though the burden of going forward to rebut the prima facie case remains with the applicant, the question of whether that burden has been successfully carried requires that the entire path to decision be retraced. An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. [HN6] Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

The similarities between the processes of Saunders and those of appellant are evident, the only significant differences alleged by appellant being: (1) the starting material (Saunders uses Alpha-methylstyrene, whereas [**10] appellant uses p-isopropenylphenol), n15/ and (2) the oxidizing agent (Saunders uses t-butylhydroperoxide, whereas appellant uses hydrogen peroxide).

n15/ The structural difference is that appellant's starting material has a hydroxyl group on the benzene ring in the para-position to the isopropenyl group: [See illustration in original.]

Regarding (1), the board noted that the generic description of Saunders' starting materials ("Alpha, Beta-unsaturated alkyl-substituted aryl compounds") encompasses appellant's starting material since the term "aryl" includes the phenyl radical. Assuming that a hydroxyl group on the benzene ring of Saunders' starting material (which is the only difference between the starting material used by appellant and that used by Saunders) would not interfere with the reaction process disclosed by Saunders, the board said that it would have been obvious to make hydroquinone (which differs from phenol only in the hydroxyl group at the para-position) from a starting material such as that used by Saunders, in which a [*1025] hydroxyl group n16/ is attached at the para-position.

n16/ Or, alternatively, a group, such as an isopropenyl group, which can be readily converted to a hydroxyl group by Saunders' process. [**11]

Regarding (2), the board noted that, although example 2 of Saunders uses t-butylhydroperoxide as the oxidizing agent, Saunders makes the general observation that hydrogen peroxide is the preferred oxidizing agent "due to its low cost." It concluded, therefore, that it would have been obvious to one skilled in the art to use hydrogen peroxide as the oxidizing agent in appellant's process. In view of the foregoing, we are persuaded that the board properly found that the prior art cited by the examiner established a prima facie case of obviousness. n17/ However, we are also persuaded that the board erred in failing to give proper weight to appellant's rebuttal affidavits, which directly attacked the premises on which the board based its determination of obviousness. Cf. *In re Lewis, supra.*

n17/ As indicated earlier, appellant has not contended that Jones was improperly applied against claims 11-13 and 16.

The only difference between Dai II and example 2 of Saunders is the presence in Dai II's starting material (the same as appellant's starting material) of a hydroxyl group on the benzene ring in the para-position. n18/ The board assumed that this difference would not interfere [**12] with the reaction process disclosed by Saunders. However, the yield of hydroquinone was dramatically less when appellant's starting material was reacted in Dai II according to Saunders' process (47%) than the yield of phenol obtained with Saunders' starting material (80%). Thus, the Dai II result contradicts both the board's assumption and its conclusion that "one of ordinary skill... [would] expect that the presence of... [one] hydroxyl group would not interfere with the process of forming the second hydroxyl group." We are satisfied that one skilled in the art, viewing the Dai affidavit, would have concluded that the presence of such a hydroxyl group results in a significantly lower yield of hydroquinone than the amount that would be obtained with the Saunders' process, and that appellant's starting material could not be readily substituted in Saunders' process to achieve similar results. n19/

n18/ This difference of a hydroxyl group results in hydroquinone being the product in Dai II, rather than phenol, which is produced in Saunders' example 2.

n19/ Contrary to the board's statement that the Dai II result conflicts with the result in example 9 of appellant's specification, the results are consistent. Under different reaction

conditions (e.g., temperature of 105 degree C in Dai II vs. 30 degree C in example 9), example 9 reports only a 32% yield of hydroquinone. This substantiates the conclusion that a significantly lower yield is achieved when appellant's starting material is used in Saunders' process. [**13]

Appellant also relies upon the published German application n20/ for its teaching that, under the process conditions of the appealed claims, both isopropenyl groups of p-diisopropenylbenzene are not readily converted to hydroxyl groups to yield hydroquinone. n21/ This teaching further supports appellant's position and contradicts the board's assumption that a first formed hydroxyl group would not interfere with the process of forming the second hydroxyl group; moreover, the low yields are in marked contrast to the substantially quantitative yields obtained by appellant.

n20/ Although the teachings of the published German application were argued before the board, it made no mention of the German application in its opinion.

n21/ The low yields of about 10-35% are obtained even though hydrogen peroxide is used as the oxidizing agent. The result of Carleton II (28%) confirms the teaching of the German application.

Finally, appellant has shown by the Dai I affidavit that, despite Saunders' observation that hydrogen peroxide is the preferred oxidizing agent because of its low cost, it would not have been obvious to one of ordinary skill in the art to use hydrogen peroxide [**14] with the starting material of appellant's process. Dai I demonstrates that when hydrogen peroxide is used in Saunders' example 2, a yield of only 15.8% [*1026] phenol is obtained in contrast to the 80% yield in Saunders' example 2. Accordingly, one skilled in the art would hardly have expected to obtain a substantially quantitative yield if hydrogen peroxide was the oxidizing agent of a different starting material from that used in Saunders' example 2.

The board's response to appellant's rebuttal evidence was:

Appellant's showing that it is possible to operate within the reference disclosure without obtaining a good yield of the desired product is insufficient to refute the teachings of the reference, since they have presented no evidence of making experiments and adaptations which one of ordinary skill in this art would make as a matter of course if he did not immediately obtain the desired results.

Although in appropriate cases such a response might be persuasive, n22/ it overlooks that the two variations from the closest prior art in the tests reported by the affidavits (different starting materials and different oxidizing agents) were the very ones that the board [**15] relied on in finding a prima facie case of obviousness. As related above, the results of those tests would negate any expectation of one skilled in the art that these variations in the Saunders' process would result in a substantially quantitative production of hydroquinone. Although there is a vast amount of knowledge about general relationships in the chemical arts, chemistry is still largely empirical, and there is often great difficulty in predicting precisely how a given compound will behave. As the Second Circuit said in *Schering Corp. v. Gilbert, 153 F.2d 428, 433, 68 USPQ 84, 89 (2d Cir. 1946):*

n22/ Cf. *In re Weber, 56 CCPA 900, 405 F.2d 1403, 160 USPQ 549 (1969); In re Michalek, 34 CCPA 1124, 162 F.2d 229, 74 USPQ 107 (1947).*

while analogy is at times useful, organic [as well as inorganic] chemistry is essentially an experimental science and results are often uncertain, unpredictable and unexpected.

Accordingly, we hold that the affidavits, when considered with all of the evidence, are sufficient as a matter of law to rebut the prima facie case of obviousness.

The rejection of claims 9-13 and 15-16 is reversed.

REVERSED [**16]

Exhibit L

In re Fay, 347 F.2d 597 (CCPA 1965)

Introduced in a response dated November 16, 2004

Acknowledged in the Office Action dated December 27, 2004

LEXSEE 146 U.S.P.Q. (BNA) 47

IN RE PHILIP S. FAY AND FRED J. FOX

No. 7352

United States Court of Customs and Patent Appeals

52 C.C.P.A. 1483; 347 F.2d 597; 1965 CCPA LEXIS 346; 146 U.S.P.Q. (BNA) 47

Oral argument February 5, 1965

June 24, 1965

PRIOR HISTORY: [**1]

APPEAL from Patent Office, Serial No. 782,641

DISPOSITION:

Reversed.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellants challenged a decision of the Patent Board of Appeals, which affirmed the patent examiner's rejection of claims in appellants' patent application as not patentable over the prior art.

OVERVIEW: Appellants disclosed and claimed leaded gasoline containing a halocarbon compound. In their specification, appellants stated that the halocarbon compounds were effective in modifying the action of the fuel in the engine through the alteration of the amount or nature of the deposits therein so as to reduce the tendency of the gasoline to pre-ignite in an engine. Appellants' arguments were based on the fact that prior art lacked factual data to support the legal conclusion of obviousness under *35 U.S.C.S. § 103;* that the use of the claimed additives did not amount to routine trials of obvious variations within the teachings of the prior art; and that the Board of Appeals did not consider the factual data in their expert's affidavit. The court held that appellants' claims were not precluded by prior art and that the affidavit contained information that the board should have considered, and reversed.

OUTCOME: The court reversed the board because it ignored the purpose for which the affidavit was submitted, viz. as evidence tending to show unobviousness of appellants' invention to one skilled in the art, and its holding was inconsistent for purposes of applying the prior art patents.

LexisNexis(R) Headnotes

Patent Law > Inequitable Conduct > General Overview
Patent Law > Nonobviousness > Evidence & Procedure > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN1] The statutory requirements for patentability are novelty, utility and unobviousness. While it is true that proof that an invention is better or does possess advantages may be persuasive of the existence of any one or all of the foregoing three requirements, and hence may be indicative of patentability, Congress has not seen fit to make such proof a pre-requisite to patentability.

Patent Law > Subject Matter > Products > Compositions of Matter

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Utility Requirement > Chemical Compounds
[HN2] Such a composition of matter is a new combination. It is necessary, therefore, to consider such a combination as an entity that embodies the invention for which a patent is sought. In other words, it is necessary to consider the invention as a whole, i.e., the mental conception of the invention as well as its embodiment in a particular composition of matter. A patentable invention is a mental result. The product is but its material reflex and embodiment.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Nonobviousness > Elements & Tests > Claimed Invention as a Whole
Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
[HN3] *35 U.S.C.S. § 103* requires that the differences between the prior art and the invention for which a patent is sought be ascertained and considered for the purpose of determining whether the claimed subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the invention pertains.

Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN4] The fact that appellants have found a limited class of materials among the necessarily large number of prior art materials is itself a factor to consider as evidence of unobviousness of the claimed invention.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues
[HN5] Resolution of the legal issue of patentability under *35 U.S.C.S. § 103* requires the court to consider what would be factually obvious to one of ordinary skill in the art. Factual data in the form of affidavits is of assistance in making this determination. Such affidavits should be given careful consideration.

COUNSEL:

Howard L. Weinshenker (Leland L. Chapman, of counsel) for appellants.

Clarence W. Moore (J. E. Armore, of counsel) for the Commissioner of Patents.

OPINIONBY:

SMITH

OPINION:

[*1483] Before RICH, Acting Chief Judge, and MARTIN, SMITH, and ALMOND, Jr., Associate Judges, and Judge WILLIAM H. KIRKPATRICK *

* United States Senior District Judge for the Eastern District of Pennsylvania, designated to participate in place of Chief Judge Worley, pursuant to provisions of Section 294(d), Title 28, United States Code. [*1484]

SMITH, Judge, delivered the opinion of the court:

Appellants appeal from a decision of the Board of Appeals, adhered to on reconsideration, affirming the examiner's rejection of claims 1-4 of appellants' application serial No. 782,641, filed December 24, 1958 and entitled "Improved Motor Fuel Composition Containing a Halocarbon Compound" as unpatentable over the prior art.

The prior art consists of the following references:

Lincoln, 2,214,768, Sept. 17, 1940.

Prutton, 2,281,598, May 5, 1942.

Calingaert et al., 2,479,900, Aug. 23, 1949.

Blaker, 2,784,160, Mar. 5, [**2] 1957.

Rudel, 2,838,387, June 10, 1958.

Newman et al., 2,937,932, May 24, 1960.

Appellants have disclosed and claimed leaded gasoline containing a halocarbon compound selected from the group consisting of 1,1-difluoro-2,2-dichloroethane, 1-fluoro-1,2,2-trichloroethane, and 1,1,1-trifluoro-2,3,3-trichloro-2-propene. Claim 1 recites the three compounds in a Markush group, while claims 2 through 4 each recite one of the three compounds individually.

In their specification, appellants state that these halocarbon compounds:

* * * are effective in modifying the action of the fuel in the engine through the alteration of the amount or nature of the deposits therein so as to reduce the tendency of said gasolines to pre-ignite in an engine.

Claim 1 reads as follows:

1. A gasoline for use in internal combustion engines containing appreciable amounts up to 3 cc. of tetraethyl lead per gallon and a fluorine-containing halocarbon compound selected from the group consisting of 1,1-difluoro-2,2-dichloroethane; 1-fluoro-1,2,2, trichloroethane; and 1,1,1-trifluoro-2,3,3,-trichloro-2-propene in an amount at least 0.5 times to 2.0 times the theoretical amount thereof required to convert [**3] the lead to lead fluoride.

It will be seen from the foregoing that appellants are claiming not only a particular class of halocarbons as an additive to gasoline containing tetraethyl lead but also the amount of such additive based on the theoretical amount required to convert the lead to lead fluoride.

Oft repeated rules, like oft repeated myths, seem to die hard. Thus, we find at the outset that the board, despite our contrary holding in *In re Ratti, 46 CCPA 976, 270 F.2d 810, 123 USPQ 349* said:

There has been no showing of superiority over any of the reference compounds and under the circumstances it may be doubted that any such showing could confer patentability. *In re Krogman, 42 CCPA 1037;* 1955 *C.D. 349; 700 O.G. 784; 223 F.(2d) 497; 106 USPQ 276.*

[*1485] [1] As we stated in Ratti, [HN1] the statutory requirements for patentability are novelty, utility and unobviousness. We repeat here what we said there: "While it is true that proof that an invention is better or does possess advantages may be persuasive of the existence of any one or all of the foregoing three requirements, and hence may be indicative of patentability, Congress has not seen fit to make such proof [**4] a pre-requisite to patentability." It seems to us, therefore, that to the extent the board's position requires an applicant to make a "showing of superiority over any of the reference compounds" it is clearly in error.

[2] We are dealing here with a composition of matter consisting of a gasoline for use in internal combustion engines to which specific amounts of specified materials have been added. As set forth in appellants' specification:

It has been discovered in accordance with this invention that a motor fuel, and particularly leaded gasoline, can be improved with respect to its tendency toward uncontrolled ignition in an engine by incorporating in the fuel a small amount of at least one fluorine-containing halocarbon compound of the group consisting of 1,1-difluoro-2,2-dichlorothane (F(2)HC-CHCl(2)); 1-fluopro-1,2,2-trichloroethane (FClHC-CHCl); and 1,1,1-trifluoro-2,3,3,-trichloro-2-propene (F(3)C-CCl-=CCl(2)). The above compounds are well known to the art and are commercially available from various sources of supply, and hence it is unnecessary herein to discuss in further detail the preparation of these compounds. * * * Therefore, this invention is based, at least [**5] in part, on the discovery of the specific group of fluorine-containing halocarbon compounds which respond in a gasoline to alleviate pre-ignition of said gasoline in an internal combustion engine.[HN2]

Such a composition of matter is a new combination. It is necessary, therefore, to consider such a combination as an entity which embodies the invention for which a patent is sought. In other words, it is necessary to consider the invention "as a whole," i.e., the mental conception of the invention as well as its embodiment in a particular composition of matter. "A patentable invention is a mental result. * * * The * * * product is but its material reflex and embodiment." *Smith v. Nichols, 88 U.S. (21 Wall.) 112 (1874).*

[3] Due to the fact that chemistry is still largely an empirical science it is easy to characterize inventions in the chemical field as but the result of "routine testing." It cannot be denied that "routine testing" is an essential part of many inventions in the chemical field. But even "routine" testing, whatever that may be, must be guided and directed by the mental concept of the inventor. It seems to us that the board lost sight of these important considerations [**6] when it stated:

With respect to the main point of the argument it is evident that appellants are experimenting with a rather small group of compounds, which it seems the art has clearly directed them to. Each of the last three mentioned patents show [*1486] chlorobromo-fluoro derivatives of ethane and Blaker may be considered as further directing them to chloro-fluoro ethanes (excluding bromine). With this as a base it can only be concluded that use of appellants' compounds amounts to routine trials of obvious variations within this extremely limited class of halohydrocarbons. It is well settled that routine experimentation within the teachings of the art is not patentable, even though some improvement may be obtained thereby. *In re Horney, 34 CCPA 968, 1947 C.D. 302, 603 O.G. 181, 161 F.(2d) 271, 73 USPQ 293; General Electric v. Watson, 127 USPQ 326;* L. Sonneborn Sons, Inc. v. Coe, 1939 *C.D. 54, 502 O.G. 4, 104 F.(2d) 230;* Sherwin-Williams Co., et al. v. Marzall, 1951 *C.D. 48, 647 O.G. 328, 190 F.(2d) 606, 89 USPQ 208;* Mandel Bros., Inc. v. Wallace, 1948 *C.D. 678, 617 O.G. 293, 335 U.S. 291, 79 USPQ 220.*

Appellants' arguments for patentability of the appealed claims are [**7] based on three points, (1) that the prior art lacks "factual data" to support the legal conclusion of obviousness under section 103, (2) that the use of the claimed additives does not amount to "routine

trials of obvious variations within the teachings of the prior art," (3) that the "Board of Appeals erred in failing to consider the factual data supplied by the Henne affidavit." We shall consider these arguments in the order stated.[HN3]

Section 103 requires that the differences between the prior art and the invention for which a patent is sought be ascertained and considered for the purpose of determining whether the claimed subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the invention pertains. Thus we look first to the prior art to determine what it discloses to the person skilled in the art of gasoline compounding.

Each of the references relied upon in the refusal of the appealed claims discloses the addition of halogenated hydrocarbons to internal combustion engine gasolines. All but Lincoln refer to alkyl lead- or tetraethyl lead-containing gasolines. While Lincoln discloses the use of [**8] halogenated cyclic compounds, Prutton teaches that combinations of halogenated hydrocarbons and oxygen-bearing compounds may be employed for the same purpose, and Rudel shows that the additives may be high molecular weight fluorinated hydrocarbons.

Blaker et al. shows the effective use as additives, for scavenger purposes, of the fluorinated hydrocarbons 1-bromo-1, 1-dichloro-2, 2, 2-trifluoroethane, 1, 2-di-bromo-1-chloro-1, 2, 2-trifluoroethane, and 1, 1, 2, 2-tetrachloro-1, 2 difluoroethane. Also, Newman et al. discloses the additive 1, 1-difluoro-2, 2-dichloro-1, 2-dibromoethane, while indicating that many other polyhalogenated hydrocarbon additives were known in the prior art. Calingaert et al. teaches that various bromine substituted hydrocarbons (having 2 to 3 bromine atoms and three to eight carbon atoms) may be employed as the additives, the invention [*1487] therein also including "the use of these scavengers with chlorohydrocarbons."

Appellants point out in their brief the differences between their invention and the disclosures of the prior art. Thus:

* * * Of the six patents on which the rejection of obviousness is based, four contain express limitations [**9] which exclude Appellants' claimed compounds. Lincoln 2,214,768:

"Among the so-called essence materials, which may be employed for the purpose of accomplishing the above-named desirable ends, are the halogenated ring compounds and more specifically the halogenated aromatic compounds" (R. 42, left column, lines 49-53).

This clearly excludes halogenated ethanes and propenes. Prutton 2,281,598:

"The halogenated oxygen-free organic compounds as noted may be either:

A. Aliphatic such as halogenated:

I. Hydrocarbons,

Notably, those containing from four to ten carbon atoms, e.g.:

Fluorinated hexane

Fluorinated octane

Fluorinated decane"

(R. 48, left column, lines 54-63)

This clearly excludes halogenated ethanes and propenes. Calingaert et al 2,479,900:

"Our invention is the use as scavengers of the class of bromine-substituted hydrocarbons having two to three bromine atoms and from three to eight carbon atoms inclusive, having not more than one bromine atom attached to any carbon atom, and having a vapor pressure at 50 degrees C. of substantially 0.2 to 6 millimeters of mercury." (R. 56, left column, lines 13-19.)

This clearly excludes halogenated ethanes and [**10] bromine-free propenes. Rudel 2,838,387:

"The compounds for use in the present invention must contain at least 14 carbon atoms and preferably at least about 22 carbon atoms." (R. 66, left column, lines 27-29.)

This clearly excludes halogenated ethanes and propenes.

The remaining two patents admittedly are the most pertinent of the lot, but their teachings are so limited that they can easily be summarized in tabular form:

Blaker 2,784,160:

Operative Compounds

(R. 61 left column, lines 55-59)

BrCl(2) C - CF(3) (halogenated ethane)

BrClFC - CF(2) Br (halogenated ethane)

Cl(2) FC - CFCl(2) (halogenated ethane)

Inoperative Compounds

(R. 63 left column, lines 1-10)

FCl(2) C - CClF(2) (halogenated ethane)

F(2) BrC - CBrF(2) (halogenated ethane)

BrH(2) C - CBrF(2) (halogenated ethane)

CCl(3) F (halogenated methane)

H(2) CBrCl (halogenated methane) [*1488] Newman et al 2,937,932:

Operative Compound

* * *

F(2) BrC - CCl(2) Br (halogenated ethane)

In summary, therefore, it is appellants' position that the six prior art patents disclose no halogenated propenes, four operative halogenated ethanes, three inoperative halogenated ethanes, and two inoperative [**11] halogenated methanes.

In their request for reconsideration of the board's decision appellants also urge that:

As was pointed out to the Examiner in an amendment dated January 31, 1961, the term "halogenated ethane" (where the halogen is F, Br, Cl or I) embraces more than 600 compounds. The field defined by the Board is somewhat narrower by the exclusion of iodine but vastly broader by the inclusion of "lower aliphatic" which embraces saturated and unsaturated compounds of varying carbon chain lengths, so that without further calculation it should be apparent that the Board's field embraces literally thousands of compounds. It is respectfully submitted that a disclosure of four operative and five inoperative compounds does not define a field embracing thousands of compounds.

If the teachings of Rudel et al are included as representative of "lower aliphatic" compounds embraced by the Board's field definition, then the carbon chain lengths run up to 14 through 22 and higher. This would add thousands upon thousands of additional compounds to the field, none of which contain less than 14 carbon atoms, and are therefore quite remote from the applicants' claimed 2 and 3 carbon [**12] atom-containing compounds.

[4] It seems to us, therefore, that [HN4] substantial differences exist between the teachings of the prior art and the invention here claimed. The fact that appellants have found a limited class of materials among the necessarily large number of prior art materials is itself a factor to consider as evidence of unobviousness of the claimed invention. See *In re Ruschig, 52 CCPA 1238, 343 F.2d 965, 145 USPQ 274.*

The board's position that appellants' invention is unpatentable is based upon its finding that Blaker, Rudel and Newman et al. "show chloro-bromo-fluoro derivatives of ethane and Blaker may be considered as further directing them [appellants] to chloro-fluoro ethanes (excluding bromine)". It is from this "base" that the board finds that appellants "are experimenting with a rather small group of compounds, which it seems the art has clearly directed them to." Predicated upon this interpretation of the prior art, the board then states, "It is well settled that routine experimentation within the teachings of the art is not patentable * * *."

[5] We question the board's position because we agree with appellants that the group of compounds to be [**13] tested is not a "rather small group" and we do not find in the art teachings which may be said to have "directed" appellants to the compounds here claimed. However, [*1489] even if the board be correct and we be in error on this point, we do not agree that "routine experimentation" negatives patentability. The last sentence of section 103 states that "patentability shall not be negatived by the manner in which the invention was made."

To support the board's decision that "routine experimentation within the teachings of the art" will defeat patentability requires a primary determination of whether or not appellants' experimentation comes within the teachings of the art. Whether the subsequent experimentation is termed "routine" or not is of no consequence.

The best one skilled in the art might glean from the prior art is that any conclusion about the operativeness of halogenated ethanes not disclosed therein would be based on pure speculation, and would be the subject of experimental testing. Many of these tests are of necessity "routine" tests, yet they must be so guided and directed as to eliminate the areas of speculation. Our conclusion in *In re Sporck, 49 CCPA 1039,* [**14] *301 F.2d 686, 133 USPQ 360,* seems particularly appropriate:

* * * Here, neither the record nor the facts of which we are able to take judicial notice supplies the factual data necessary to support the legal conclusion of obviousness of the invention at the time it was made. We are unwilling to substitute speculation and hindsight appraisal of the prior art for such factual data. For this reason we think there is a doubt as to the factual basis supporting the conclusion of the board of appeals that the invention would have been obvious to one of ordinary skill in the art of metal spinning. Under these circumstances, the doubt should be resolved in favor of the applicant. *In re Devine, 46 CCPA 725, 261 F.2d 240, 120 USPQ 84; In re Altmann and Bureau, 46 CCPA 818, 264 F.2d 894, 121 USPQ 262.*

In the present case, appellants' invention is not concerned with optimizing proportions of prior-art compounds, nor is the prior art so replete with operative examples of halogenated ethanes and propenes that it can be said that a line of investigation of further compounds has been indicated.

We pass now to the asserted error of the board in refusing to consider the factual data supplied [**15] by

the Henne affidavit. The role of affidavits in resolving the legal issue of obviousness under section 103 is well established. We stated in *In re Lulek, 49 CCPA 1323, 305 F.2d 864, 134 USPQ 352:*

[HN5] Resolution of the legal issue of patentability under *35 U.S.C. 103* requires us to consider what would be factually obvious to one of ordinary skill in the art. Factual data in the form of affidavits is of assistance in making this determination. We think such affidavits should * * * be given careful consideration.

[6] The board stated that the Henne affidavit is essentially an opinion and as such carries little weight. It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated [*1490] compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion.

In [**16] reviewing the board's decision it seems to us that it does not relate the factual data in the affidavit to the issue of unobviousness. Rather the board stated:

* * * Henne's observance of distinctions in the bonding and splitting of the hydrocarbons beginning at the bottom of page 4 and running through page 5 of the affidavit, seems to us to be of little significance when appellants profess ignorance of the precise action of these halohydrocarbons in the gasoline engine.

This holding of the board is erroneous for two reasons. First, it ignores the purpose for which the affidavit was submitted, viz. as evidence tending to show unobviousness of appellants' invention to one skilled in the art. Second, the board's holding is inconsistent with its treatment of the "action" of appellants" holohydrocarbons for purposes of applying the prior art patents. In this latter context, the board stated:

* * * Appellants profess not to know the precise action of their halogenated hydrocarbons, but for convenience they may be regarded as scavenging agents. [Emphasis added.]

The factual data in the Henne affidavit consists of an enumeration of basic chemical differences between appellants' [**17] claimed compounds and those of the prior art. Thus, in discussing the criticality of the presence of fluorine in a halogenated compound, Dr. Henne stated:

In organic compounds, we are, * * * concerned with * * * the bonding or bondings they [the halogens] can make with carbon.

Fluorine and carbon are both in the same horizontal period of the table and any bonding they make between themselves will be, from both sides, at the same principal quantum number, namely 2.

By contrast, all the other halogens can only be bonded to carbon at differing quantum numbers (3 for chlorine, 4 for bromine, etc.). There is, therefore, a basic difference between carbon-fluorine bonds on the one hand, and carbon-chlorine, carbon-bromine and carbon-iodine bonds on the other hand.

This difference in bonding leads me to the conclusion that the knowledge of what non-fluorinated halocarbon compounds will accomplish in the high temperature environment of a combustion chamber, would not permit me to predict what fluorinated halocarbon compounds would accomplish in the same environment.

The Henne affidavit presents factual data which appears to show that the presence or absence of hydrogen atoms [**18] in the halocarbon compound influences the behavior of the perhalogenated paraffins in [*1491] the high temperature environment of the combustion chamber of an internal combustion engine.

The board's statement that the prior art clearly directed appellants to their claimed compounds ignores the existence of the chemical differences discussed in the Henne affidavit. Moreover, the skilled artisan recognizing, as Henne did, that these chemical differences are responsible for the formation of thermal decomposition products different from those formed from the prior art halohydrocarbon additives, and recognizing further from the teachings of the Blaker patent the inoperativeness of certain halocarbon compounds more closely related to the operative prior art compounds than to appellants' compounds, would not be "clearly directed" to appellants' claimed compounds.

In view of the foregoing, the decision of the board is reversed.

Exhibit M

Related Proceedings Appendix

Decision on Appeal for patent application U.S. Serial No. 09/785,936

Appeal No. 2004-0450

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THEODORE M. WONG,
DAVID A. SINGER, and
SANTA H. LIN

Appeal No. 2004-0450
Application No. 09/785,936

ON BRIEF

Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 79 through 94, 97 through 111, 113 through 118, and 120 through 129, which are all of the claims remaining in this application. The claims have been grouped together (Appeal Brief, page 4). Accordingly, for the purposes of this appeal, we shall treat all claims as standing or falling with representative claim 79:

79. A method for producing a purified vegetable protein material having low concentrations of ribonucleic acids, phytic acid, and phytates, comprising:

forming an aqueous slurry of a vegetable protein material and an enzyme preparation containing an acid phosphatase enzyme and a phytase enzyme, wherein said enzyme preparation is present in said slurry in an amount relative to the protein material of from about 0.1% to about 10% by weight of the protein material (dry);

treating the slurry containing the protein material and the enzyme preparation at a temperature, a pH, and for a time period effective to enable said acid phosphatase enzyme to degrade ribonucleic acids in the vegetable protein material and to enable said phytase to degrade phytic acid and phytates in the vegetable protein material; and

washing the vegetable protein material after treatment to degrade ribonucleic acids, phytic acid, and phytates to provide a vegetable protein material having reduced concentrations of ribonucleic acids, phytic acid, and phytates.

In rejecting applicants' claims on prior art grounds, the examiner relies on the following reference:

European Patent Application	0 380 343 A2	Aug. 1, 1990

All of the appealed claims stand rejected under 35 U.S.C. § 102 or § 103 as unpatentable over European Patent Application 0 380 343 A2 ('343 patent). We shall affirm this rejection.

PROCEDURE

To dispel ambiguity, we shall first clarify what evidence is of record. On June 17, 2003, applicants filed a Reply Brief (Paper No. 16) with three exhibits attached: a BASF

publication describing the phytase Natuphos® (Exhibit A); the Wong declaration (Exhibit B); and the Taylor declaration (Exhibit C).

As stated in 37 CFR § 1.195,

> Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

The examiner, however, did not invoke that rule to deny entry of Exhibits A, B, or C, despite the absence of "a showing of good and sufficient reasons why they were not earlier presented." Rather, in the Office communication mailed September 11, 2003 (Paper No. 17), the examiner stated that "[t]he reply brief filed June 17, 2003 has been entered and considered." In our judgment, the only plausible interpretation which these facts permit is that the examiner considered and made of record Exhibits A, B, and C. This follows because, in their Reply Brief, applicants set forth arguments based on those exhibits, and the examiner entered and considered the Reply Brief.

Additionally, applicants' main Brief (Paper No. 14), received January 29, 2003, includes Appendix C and Appendix D. The former was filed before the Final Rejection in this application and is clearly of record. The latter was filed with the main Brief. Again, however, the examiner did not invoke the provisions of 37 CFR § 1.195 to deny entry of Appendix D. On contrary, the examiner has considered and discussed Appendix D in the Answer, page 13, first full paragraph. It is apparent, therefore, that Appendix D has been entered and made of record.

THE MERITS

Claims 79 through 94, 97 through 111, 113 through 118, and 120 through 129 stand rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over the '343 patent. This reference discloses a method for producing a phytate-free or low phytate soy protein isolate and concentrate using one or more phytate-degrading enzymes. The '343 patent discloses phytate-degrading enzymes which include phytases and acid phosphatases. "Particularly preferred for the purposes of the present invention are the Finase enzymes" ('343 patent, page 6, line 26). It is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase.[1]

The examiner's main argument is that, although the prior art does not explicitly disclose the degradation of RNA, a person having ordinary skill in the art, armed with the disclosure of the '343 patent and carrying out its method using the preferred enzyme, Finase, would inevitably and necessarily degrade RNA present in the soy protein.[2]

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[1] "A combination of phytase and a pH 2.5 optimum acid phosphatase form A. niger has been used by Alko, Ltd. as an animal feed supplement in their phytic acid degradative product Finas [sic] F and Finase S." U.S. Patent No. 6,190,897 issued February 20, 2001, to Kretz, column 2, lines 18 through 22 (copy enclosed with this opinion).

[2] See the Final Rejection (Paper No. 9, page 3), "the degradation of RNA is inherent to the enzyme digestion of the vegetable protein as disclosed by the cited reference;" and see the Examiner's Answer (Paper No. 15, page 5), "RNAs are inherently degraded by the acid phosphatase present in the Finase enzyme of the cited disclosure."

According to applicants, claim 79 is not anticipated by the cited prior art because:

> [T]he '343 patent does not disclose 1) the degradation of ribonucleic acids; 2) where the ribonucleic acid degradation is effected with an acid phosphatase enzyme; or 3) the formation of an aqueous slurry or mixture of vegetable protein material and an acid phosphatase enzyme or an enzyme preparation containing an acid phosphatase enzyme, where the acid phosphatase enzyme or enzyme preparation is present in the slurry or mixture in an amount of from about 0.1% to about 10% by weight of protein material (dry). [Appeal Brief, page 6]

RNA Degradation

The '343 patent does not explicitly mention RNA or the degradation of RNA. Nonetheless, applicants acknowledge that

> Commercially available protein concentrates and isolates . . . contain some impurities which are undesirable in products such as infant formulas. Specific impurities which are undesirable in vegetable protein isolates and concentrates include phytic acid, phytates, ribonucleic acids, ash, and minerals bound to phytic acid, phytates, or ribonucleic acids which are unavailable for human assimilation such as phosphorus, calcium, chloride, iron, zinc, and copper. It is desirable to provide methods for reducing the levels of these impurities in vegetable protein isolates and concentrates, particularly for use in products such as infant formulas. [Specification, page 1, lines 12 through 19]

According to applicants, "[p]hytase enzyme compositions are not recognized to reduce the levels of ribonucleic acid materials and associated minerals in vegetable protein materials since the most common phytases . . . do not degrade the ribonucleic acid structure." (Id., page 2, lines 26 through 29).

Applicants have attached several publications to their Appeal Brief and Reply Brief as support for this argument. For example, according to applicants, the Leach

publication (Appendix C of the Brief) teaches that "one skilled in the art would not expect phosphatases to degrade polymeric nucleotides such as ribonucleic acids" (Appeal Brief, page 13, first full paragraph). Also, the Cech patent (Appendix D of the Brief) "illustrates that one skilled in the art separately classifies RNA cleaving enzymes (endoribonucleases) from dephosphorylating enzymes such as acid phosphatase (dephosphorylases)" (Id.). According to applicants, the BASF publication (Exhibit A of the Reply Brief) and the Wong declaration (Exhibit B of the Reply Brief) further support this line of argument. See applicants' Reply Brief, pages 5 and 8.

Applicants argue that their claimed invention "is not inherently anticipated by the '343 patent since the '343 patent does not necessarily require the use of an acid phosphatase enzyme to produce a phytate-free or low-phytate soy protein, and, therefore, degradation of ribonucleic acids with an acid phosphatase enzyme cannot be a necessary consequence of, does not naturally flow from, and is not always present in the method disclosed in the '343 patent" (Appeal Brief, page 7, first full paragraph, emphasis added).

We disagree with that reasoning. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Additionally, even when processes "encompassed by the claims are not entirely old, the rule is applicable . . . to the extent that the claims and the prior art overlap." Id.

It appears to us that applicants have merely discovered and are claiming a new benefit of the method disclosed in the '343 patent where Finase is employed as the enzyme preparation. As stated by applicants:

> The present invention resides in the discovery that acid phosphatase enzymes unexpectedly cleave ribonucleic acids . . . [a]lthough certain commercially available phytase enzyme preparations include acid phosphatases, it has not been previously recognized that acid phosphatases are useful for degrading ribonucleic acids, and that the concentration of ribonucleic acids in vegetable protein materials can be reduced by treatment with an acid phosphatase. [Specification, page 4, first full paragraph]

and

> Applicants agree with the Examiner's statement that the reference clearly teaches use of an enzyme preparation that contains an acid phosphatase, and that such an enzyme preparation is utilized in an aqueous suspension of a soy protein material. Applicants would also agree that RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent. [Appeal Brief, page 8, second full paragraph, emphasis added].

We emphasize here that Finase, an enzyme preparation containing acid phosphatase, is particularly preferred for the purposes of carrying out the invention disclosed in the '343 patent. See the '343 patent, page 6, lines 26 and 27; and see comparative examples 2 through 5, pages 7 through 10. The cited prior art reference puts a person having ordinary skill in possession of the disclosed embodiment using Finase enzymes.[3]

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[3] Exhibit C attached to the Reply Brief is the Taylor declaration, filed under the provisions of 37 CFR § 1.132, executed June 17, 2003. In paragraph 5, declarant refers to the following statement in the Appeal Brief, page 8, second full paragraph: "Applicants would also agree that RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343

(continued...)

Applicants argue that "for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference" (Appeal Brief, bottom of page 6, citing Mehl/Biophile International Corp. v. Milgraum, 192 F.3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999)). Therefore, according to applicants, because "the '343 patent does not require the use of an acid phosphatase enzyme to degrade phytates, although such an enzyme may be used . . . degradation of RNA in a vegetable protein with an acid phosphatase is not always present and is not a necessary consequence of the '343 patent (Id., page 9, emphasis added). Applicants thus argue a "may" versus "must" distinction. According to applicants,

> the reference teaches processes that may utilize an enzyme preparation that contains an acid phosphatase enzyme in a vegetable protein material, but does not teach that the enzyme preparation must contain an acid phosphatase enzyme --- regardless of the exclusive use of FINASE® enzyme preparations in the comparative examples of the reference. [Reply Brief, page 3, first full paragraph].

Again, "the reference discloses that use of the FINASE® enzyme preparations is a preferred method of practicing the disclosed invention, but that the process of the reference is not limited to use of FINASE® enzymes and can utilize any phytate-degrading enzyme preparation containing one or more phytate-degrading enzymes"

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[3](...continued)
patent." According to declarant, that statement "was made in light of knowledge provided by the invention;" it "was not directed to explain the knowledge of those skilled in the art at or before the invention of the present patent application." It can be seen that paragraph 5 of the Taylor declaration is consistent with our determination that appellants have discovered and are claiming a new benefit of the method disclosed in the '343 patent where Finase is employed as the enzyme preparation.

(Id., page 4). Applicants argue that "[t]he cited reference, therefore, clearly did not intend to limit the disclosed method of reducing phytates and phytic acids to using only FINASE® enzyme preparations" (Id., page 5, first full paragraph). The argument lacks merit.

The '343 patent discloses the use of Finase enzymes as a particularly preferred embodiment. See the '343 patent, page 6, lines 26 and 27; and see comparative examples 2 through 5, pages 7 through 10. Again, it is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase; and applicants acknowledge that RNA would be degraded by using an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent (Appeal Brief, page 8, second full paragraph). In our judgment, a person having ordinary skill in the art, given the disclosure of the '343 patent and its preferred embodiment using Finase enzymes, would inevitably and necessarily degrade RNA in the manner recited in claim 79. That a person having ordinary skill may work within the broad disclosure of the '343 patent without using Finase, or that the '343 patent discloses non-preferred embodiments, does not detract from the examiner's position. The '343 patent clearly and unequivocally discloses the use of Finase, and puts a person having ordinary skill in possession of the embodiment using Finase. Admittedly, RNA is degraded when using Finase in the method of the '343 patent.

Enzyme Concentration

Applicants also argue that "the '343 patent does not inherently disclose that the acid phosphatase enzyme is present in the mixture of enzyme and vegetable protein material in an amount relative to the protein material of from about 0.1% to about 10% by weight of the protein material (dry)." (Appeal Brief, page 9, first full paragraph). Applicants acknowledge that enzyme dosages in the '343 patent "are presented as phytate-degrading units/g [soy] flakes" (the '343 patent, page 8, line 2). Nonetheless, according to applicants, "an enzyme activity level is not equivalent to a specified amount or concentration of an enzyme---it merely discloses how active the enzyme is. By definition, enzyme activity is the amount of an enzyme preparation required to effect a defined amount of a specific reaction in a defined amount of time." (Id., page 10, first full paragraph). The argument lacks merit.

The '343 patent clearly and unequivocally discloses using Finase enzymes in an aqueous suspension of a soy protein material; and it is undisputed on this record that Finase is a commercially available enzyme preparation containing both phytase and acid phosphatase. The use of Finase is particularly preferred for the purposes of carrying out the invention disclosed in the '343 patent, and its use is illustrated in comparative examples 2 through 5, pages 7 through 10. The reference puts a person having ordinary skill in possession of the disclosed embodiment using Finase, and applicants acknowledge that RNA would be degraded by using an enzyme preparation containing acid phosphatase in the method of the '343 patent. It appears reasonable to

say, therefore, that the amount of enzyme preparation used in the '343 patent is the same or substantially the same as the amount recited in claim 79. On these facts, the burden of persuasion shifted to applicants to establish a difference between the amount of enzyme preparation recited in claim 79 and the amount disclosed in the prior art reference. This applicants have not done. Applicants have presented no objective evidence or data on this record to show that the amount of enzyme used in the prior art is distinguishable from the amount recited in claim 79. In fact, applicants agree that "RNA would be degraded by use of an enzyme preparation containing an acid phosphatase enzyme in the method of the '343 patent" (Appeal Brief, page 8, second full paragraph). Compare In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote and citations omitted].

Nor does the disclosure of a non-preferred embodiment in the '343 patent detract from the examiner's position.

CONCLUSION

Accordingly, for the reasons set forth in the body of this opinion, we affirm the rejection of claim 79 under 35 U.S.C. § 102 or 35 U.S.C. § 103. As previously indicated, claims 80 through 94, 97 through 111, 113 through 118, and 120 through 129 fall together with claim 79.

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES